

**A DOUBLE BLIND RANDOMISED CONTROL STUDY TO ANALYSE  
THE CLINICAL OUTCOMES BETWEEN THE TWO-STRAND MODIFIED  
KESSLER REPAIR AND THE FOUR-STRAND CRUCIATE MCLARNEY  
REPAIR TECHNIQUES FOLLOWING PASSIVE MOTION PROTOCOL IN  
ADULTS**

Dissertation submitted

In partial fulfillment for the award of

M.S DEGREE EXAMINATION

M.S ORTHOPAEDIC SURGERY

CHRISTIAN MEDICAL COLLEGE & HOSPITAL, VELLORE- 4



SUBMITTED TO

THE TAMILNADU DR.MGR MEDICAL UNIVERSITY

CHENNAI-32

APRIL-2015



**A DOUBLE BLIND RANDOMISED CONTROL  
STUDY TO ANALYSE THE CLINICAL  
OUTCOMES BETWEEN THE TWO-STRAND  
MODIFIED KESSLER REPAIR AND THE  
FOUR-STRAND CRUCIATE MCLARNEY  
REPAIR TECHNIQUES FOLLOWING PASSIVE  
MOTION PROTOCOL IN ADULTS**

**Dr. Santhosh Kumar. G**  
**Department of Orthopaedics**  
**Christian Medical College, Vellore.**



DEPARTMENT OF ORTHOPAEDICS  
CHRISTIAN MEDICAL COLLEGE & HOSPITAL  
VELLORE

This is to certify that this dissertation titled “**A DOUBLE BLIND RANDOMISED CONTROL STUDY TO ANALYSE THE CLINICAL OUTCOMES BETWEEN THE TWO-STRAND MODIFIED KESSLER REPAIR AND THE FOUR-STRAND CRUCIATE MCLARNEY REPAIR TECHNIQUES FOLLOWING PASSIVE MOTION PROTOCOL IN ADULTS**” has been prepared by **Dr.SANTHOSH KUMAR.G**, under my supervision in the Dr Paul Brand Centre for Hand Surgery, Leprosy Recon. Surgery and Peripheral Nerve Surgery, Christian Medical College Hospital, Vellore during the academic period 2013-2015 and is being submitted to the Tamil Nadu Dr.MGR Medical University, Chennai in partial fulfillment of the University regulation for the award of Degree of M.S Orthopaedic Surgery and his dissertation is a bonafide work.

**Dr. Alfred Job Daniel**  
**D. Ortho, M.S. Ortho, DNB Ortho**  
**Principal**  
**Christian Medical College**  
**Vellore - 632 004.**

Vellore:

Date:



DEPARTMENT OF ORTHOPAEDICS  
CHRISTIAN MEDICAL COLLEGE & HOSPITAL  
VELLORE

This is to certify that this dissertation titled “**A DOUBLE BLIND RANDOMISED CONTROL STUDY TO ANALYSE THE CLINICAL OUTCOMES BETWEEN THE TWO-STRAND MODIFIED KESSLER REPAIR AND THE FOUR-STRAND CRUCIATE MCLARNEY REPAIR TECHNIQUES FOLLOWING PASSIVE MOTION PROTOCOL IN ADULTS**” has been prepared by **Dr.SANTHOSH KUMAR.G**, under my supervision in the Dr Paul Brand Centre for Hand Surgery, Leprosy Recon. Surgery and Peripheral Nerve Surgery, Christian Medical College Hospital, Vellore during the academic period 2013-2015 and is being submitted to the Tamil Nadu Dr.MGR Medical University, Chennai in partial fulfillment of the University regulation for the award of Degree of M.S Orthopaedic Surgery and his dissertation is a bonafide work.

**Dr. Vernon N Lee**  
**D. Ortho, M.S. Ortho, Mch,**  
**Professor and Head**  
**Department of Orthopaedics**  
**Christian Medical College**  
**Vellore - 632 004.**



DEPARTMENT OF ORTHOPAEDICS  
CHRISTIAN MEDICAL COLLEGE & HOSPITAL  
VELLORE

This is to certify that this dissertation titled “**A DOUBLE BLIND RANDOMISED CONTROL STUDY TO ANALYSE THE CLINICAL OUTCOMES BETWEEN THE TWO-STRAND MODIFIED KESSLER REPAIR AND THE FOUR-STRAND CRUCIATE MCLARNEY REPAIR TECHNIQUES FOLLOWING PASSIVE MOTION PROTOCOL IN ADULTS**” has been prepared by **Dr.SANTHOSH KUMAR.G**, under my supervision in the Dr Paul Brand Centre for Hand Surgery, Leprosy Recon. Surgery and Peripheral Nerve Surgery, Christian Medical College Hospital, Vellore during the academic period 2013-2015 and is being submitted to the Tamil Nadu Dr.MGR Medical University, Chennai in partial fulfillment of the University regulation for the award of Degree of M.S Orthopaedic Surgery and his dissertation is a bonafide work.

**Dr.Binu Prathap Thomas.**  
**D.Ortho.M.S.Ortho,PDFHS(USA)**  
**Professor & Head**  
**Dr Paul Brand Centre for Hand Surgery, Leprosy**  
**Recon. Surgery and Peripheral Nerve Surgery**  
**Christian Medical College**  
**Vellore - 632 004.**



## DECLARATION

I, **Dr. SANTHOSH KUMAR.G**, solemnly declare that the dissertation , “**A DOUBLE BLIND RANDOMISED CONTROL STUDY TO ANALYSE THE CLINICAL OUTCOMES BETWEEN THE TWO-STRAND MODIFIED KESSLER REPAIR AND THE FOUR-STRAND CRUCIATE MCLARNEY REPAIR TECHNIQUES FOLLOWING PASSIVE MOTION PROTOCOL IN ADULTS** ” is a bonafide work done by me in the Department of Orthopaedic Surgery, Christian Medical College Hospital, Vellore under the guidance of Prof. Binu Prathap Thomas, Dr Paul Brand Centre for Hand Surgery, Leprosy Recon. Surgery and Peripheral Nerve Surgery, Christian Medical College, Vellore.

Place: Vellore

Signature

Date:

(SANTHOSHKUMAR.G)

## ACKNOWLEDGEMENT

It gives me a great pleasure in preparing this dissertation and I take this opportunity to thank everyone who made this possible.

It is most appropriate that I begin by expressing my gratitude to the almighty for his entire blessing.

It is with immense gratitude that I acknowledge the support and sincere debt of gratitude to **Professor. Binu Prathap Thomas**, Head of Dr Paul Brand Centre for Hand Surgery, Leprosy Recon. Surgery and Peripheral Nerve Surgery for his patience and valuable advice, without which this work would have never attained the present shape.

I take this opportunity to thank my co guides and investigators Associate Professor **Dr. Anil Mathew**, Assistant Professor **Dr. Kiran Sasi** and **Dr. Sreekanth .**

I am indebted to my many colleagues who supported me and the hand physiotherapist for their overwhelming support forever.

I would like to extend my thank to Research board Christian medical college and the Biostatistics Department for providing me all necessary material for my study.

I owe my deepest gratitude to my wife, parents and friends, for their cooperation.

I will be failing in my duty, if I do not express my gratitude to all patients who were subjects of the study.

Date:

**Signature of candidate**

Place:

**Dr. Santhosh Kumar. G**



## **ABSTRACT**

The purpose of the study is to evaluate the clinical outcome between the 2-Strand Modified Kessler repair and 4-Strand McLarney repair technique in adults following a Kleinert passive motion protocol. We repaired 54 flexor tendon lacerations in a duration of 6 months. We randomized and tendons were repaired with either 2-Strand or 4-Strand McLarney technique. The TAM (Total Active Motion) was calculated from post op 2 months to 6 months and scored by ASSH score. The tensile strength was measured using digital hand held dynamometer after 6 months. There was no rupture in either of the two groups. The statistical analysis was done. In conclusion, there is no statistical difference between two-strand (Modified Kessler) and four-strand (McLarney) techniques of flexor tendon repair following a Kleinert Passive Motion Protocol in terms of rupture, total active motion, grip strength and adhesion on in vivo testing.

**Keywords:** Modified Kessler repair, McLarney repair, Kleinert Passive Motion Protocol, total active motion, grip strength

## CONTENTS

S. NO	TITLE	PAGE NO
1	INTRODUCTION	
2	REVIEW OF LITERATURE	
3	AIM OF THE STUDY	
4	METHODOLOGY	
5	RESULTS	
6	DISCUSSION	
7	CONCLUSION	
8	REFERENCES	
9	ANNEXURES	

# INTRODUCTION

“A man’s best friends are his ten fingers”<sup>1</sup>. The complete use of one’s “best friends” requires intact flexor tendons. The flexor tendon injuries are caused by volar lacerations. Flexor tendon injuries has been treated by Hippocrates, Galien and Avicenne<sup>2</sup>. The first successful flexor tendon grafting was done in 1910 by K. Biesalski, in 1912 by E.Lexer and in 1916 by L.Mayer. The direct repair in zone II was first successfully done by H.Kleinert in 1967<sup>3</sup>.

There are different techniques of tendon repair 2-Strand, 4-Strand, 6-Strand and 8-Strand. There are literature which described about the difference in strength of these different techniques in vitro to prove that the, rupture rate and tensile strength of the 4-Strand repair technique is superior to 2-Strand, the more the core stitch the strength is increased<sup>32,33,34</sup>.

The ideal tendon repair should have anatomical tendon approximation, easy placement of suture, secure knots, minimal interference with blood supply and early mobilisation<sup>4</sup>. These principles should be followed in whatever the technique of repair is used.

The study purpose is to evaluate the clinical outcome between the two types of tendon repair technique 2-Strand modified Kessler and 4-Strand McLaren in vivo in adults.

# **ANATOMY OF FLEXOR TENDONS OF THE HAND**

The long flexors of the hand are flexor digitorum superficialis (FDS) and flexor digitorum profundus(FDP).

FLEXOR DIGITORUM SUBLIMUS(SUPERFICIALIS) :

The flexor digitorum sublimus is one of the superficial flexors of the forearm. It lies in the superficial volar compartment of the forearm. The FDS is located deep to flexor carpi radialis and palmaris longus. The flexor carpi ulnaris lies superficial and ulna to FDS. The FDS has two heads humeroulnar and radius head. The humeroulnar head have several sites of origins from the common flexor origin the medial epicondyle, from the anterior band of ulnar collateral ligament, from medial intermuscular septum and from the medial side of coronoid. The radial head is long thin muscular sheet of attachment from the proximal third of radius. The median nerve and ulna artery passes through the muscular arch formed by this two heads. The ulna side muscle fibres extend distally in a vertical fashion and radial side fibres extend obliquely and form a common muscle belly.

The common muscle belly forms a superficial and deep plane of fibres. The superficial plane of fibres divide into two, to form tendons of long and ring fingers and the deep fibres divide into two, to form the tendons of index and little fingers. This arrangement is retained at the wrist level in the carpal tunnel. The tendons of long and ring fingers are located superficial and central. The tendons of index finger and little finger are located deep in the radial and ulna

side. The tendons extend distally in the palm deep to superficial palmar arterial arch and digital nerves. At the level of proximal phalanx they divide into two slips and the interval between the divergence of two slips the FDP passes. The two slips of FDS rotate 90 to 180 degree and encircle the profundus tendon. The two slips reunite at the Camper's chiasma. The FDS slips decussate in "X" pattern at the level of Camper's chiasma and passes distally to attach to distal part of middle phalanx.(Figure 1)

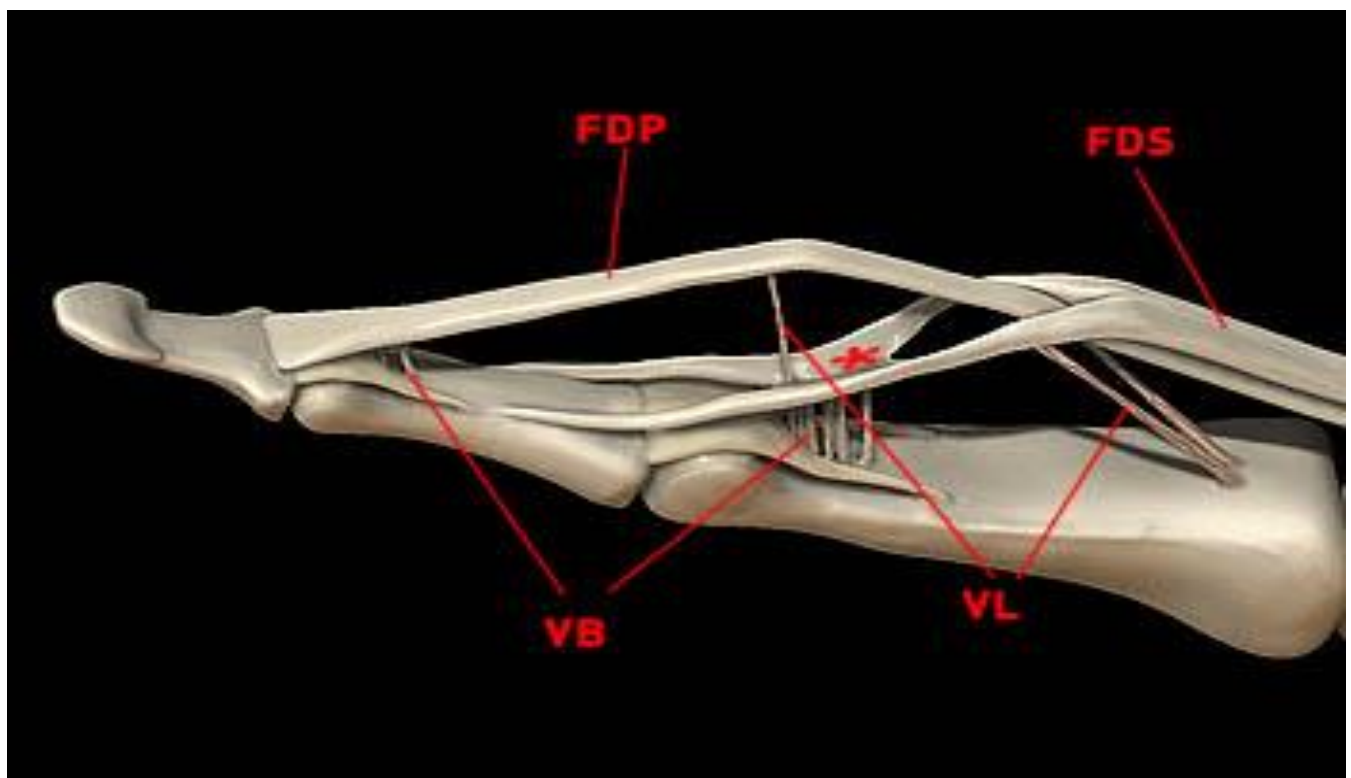


Figure 1: Illustration of the FDS slip

The vascular supply to the tendon is from the longitudinal vessels that enter into the palm and extends to intratendinous channel, digital arteries that enter by means of short and long vincula, vessels that enter at the level of proximal synovial fold in the palm and the vessels that enter at the osseous insertion of FDS. In the digital sheath the vascular supply to the tendon is through short and long vincula. The vincula include the vinculum brevis superficialis, vinculum longum superficialis, vinculum brevis profundus and vinculum longum profundus. In addition the tendon receive nutrition from synovial fluid in the synovial sheath. The vascularity of the dorsal half of the tendon is higher because the vincula enter the tendon in the dorsal surface.

(Figure 2)

The innervation of the FDS is by median nerve. The nerve trunk exits the median nerve proximal to pronator teres and accompanies the main trunk through two heads of pronator teres. Then the branch divides into multiple small branches which supplies the radial head of the muscle. The muscle portion that forms tendons of index and little finger receive a separate motor branch.

The FDS function is to flex the PIP joint of index, middle, ring and little fingers. They also contribute in MCP joint flexion and wrist flexion. The FDS has individual muscle component for each four fingers so it can flex independently the PIP joint.



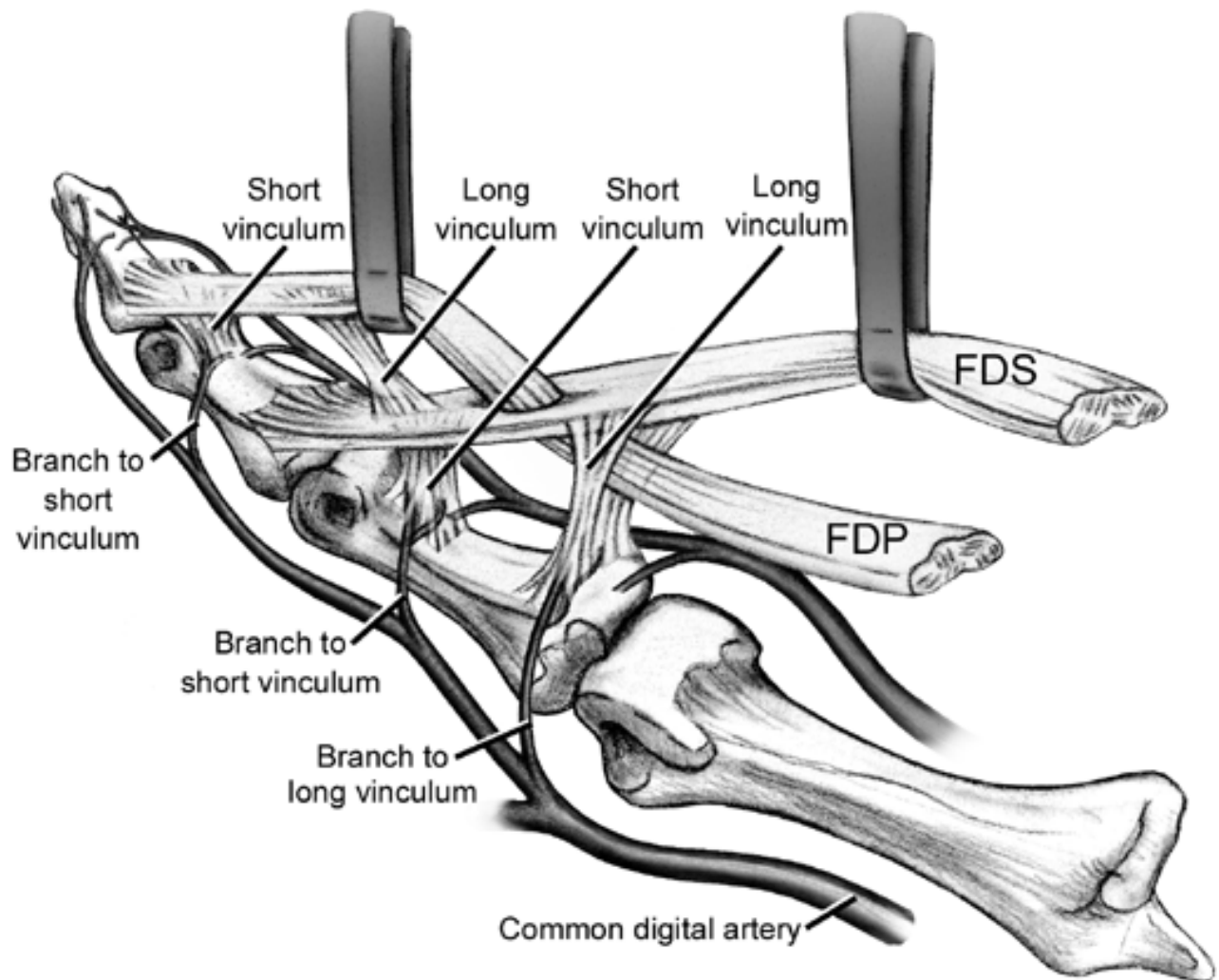


Figure 2: Illustration of the vinculum

### **Variations and Anomalies :**

The most common anomalies are muscle slips interconnect with other forearm flexors, the flexor pollicis longus and the palmaris longus or the brachioradialis. The variations are more common in index and little fingers<sup>5</sup>.

### FLEXOR DIGITORUM PROFUNDUS(FDP):

The FDP, is one of the deep flexors of the forearm lies in the deep volar compartment in the ulnar side of the interosseous membrane. The FDP is covered anteriorly by FDS and FCU. The median nerve courses between the superficial and deep flexor compartment. The FDP has extensive origin, it includes the proximal two third of the ulna anterior and medially, medial portion of the coronoid process and the interosseous membrane. The extensive origin forms a single muscle belly but the belly of index finger is separate and discernible.

The myotendinous junction is at the central third of the forearm and muscle attachment is more dorsal than volar. The myotendinous junction give rise to four tendons which run parallel to each other from radial to ulna and extends distally to the index, long, ring and little fingers respectively. The muscle bellies to the long, ring and little finger interconnected by areolar tissue from forearm to palm. The muscle and tendon of index finger is distinct throughout the course. The tendon extends distal to the FDS in the carpal tunnel and then tendon diverge to each digit in the palm.

At the distal margin of the carpal tunnel the lumbricals arise from the FDP tendon. The FDP tendon enters the A1 pulley just proximal to the MCP joint. In the digits at the level of the proximal phalanx the FDP enters the FDS

split and continues distally to insert into the base of the distal phalanx. The vascular supply is grossly same as FDS.

The FDP is innervated by both median nerve through anterior interosseous nerve supplies the muscle bellies of index and long finger and by the ulnar nerve supplies the muscle bellies of the ring and little. The anterior interosseous nerve exits the nerve trunk before the median nerve enters between the two heads of pronator teres. The anterior interosseous nerve enters the fibromuscular arch formed by origins of FDS. The AIN then divides into multiple branches to supply the index and long finger muscle bellies. The ulnar nerve innervation is through a motor branch at the level of elbow.

The FDP main action is to flex the DIP joint it also assists in flexion of PIP with FDS and MCP with lumbricals and interossei.

### **Variations and anomalies :**

The most common variations are accessory muscles or tendinous slips from the FDP to radius, FPL, FDS, to the medial epicondyle and coronoid process<sup>5</sup>.

## **PULLEY SYSTEM OF THE WRIST AND HAND**

### **WRIST**

Kline and Moore in 1992 proposed that the Transverse Carpal Ligament (TCL) is an important component of the flexor pulley system (figure. 3). This broad ligament, which spans the palmar side of the carpus, in its absence there is a 25% increase in the excursion of the profundus and a 20% increase in the superficialis. This resulted in less remaining excursion for flexion of the other joints and contributed to weakness of grip.

The main purpose of the TCL is to act as a flexor pulley at the wrist. This increase in flexor tendon excursion was demonstrated only when the wrist in flexed position. This resulted in decreased grip strength when the wrist is flexed. This shows the importance of knowing the status of all three components the wrist, palm, and finger before performing flexor tendon surgery<sup>5</sup>.

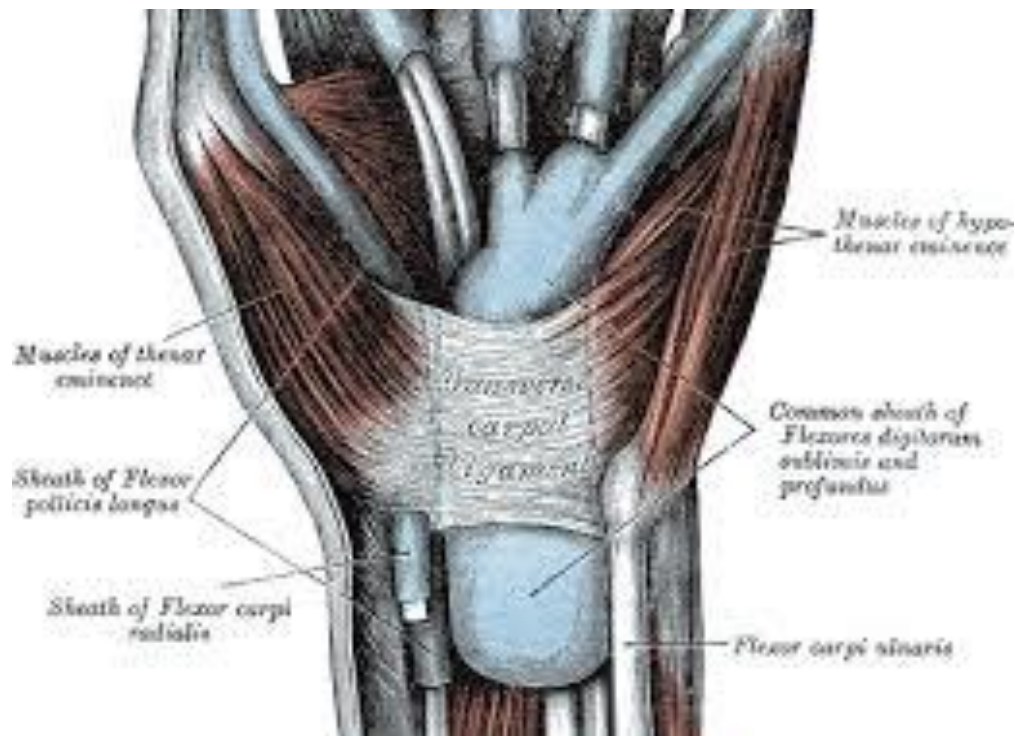


Figure 3 : Depiction of the transverse carpal ligament.

### PALMAR APONEUROSIS PULLEY

In 1983 Manske and Lesker, described the palmar aponeurosis pulley system. This is formed by the transverse fibers of the palmar aponeurosis that are anchored to flexor synovial sheath on each side by vertical (sagittal) fibers, which is attached to the deep transverse metacarpal ligament and form an archway over the flexor tendons. Its average width is 9.3 mm, and the proximal edge begins 1 to 3 mm distal to the flexor synovial sheath. Manske and Lesker noted that preservation of total range of finger motion, if the palmar aponeurosis pulley was intact even in absence of the critical A1 and A2 pulleys. The loss of

flexion is insignificant with the absence of the A1 or A2 pulley when the palmar aponeurosis pulley is present. If the loss of flexion increases in the absence of the A1 or A2 pulley it is due to combined absence of the palmar aponeurosis pulley. The single functioning pulley, the A2 pulley was most important, followed by the A1 pulley.( Figure 4)

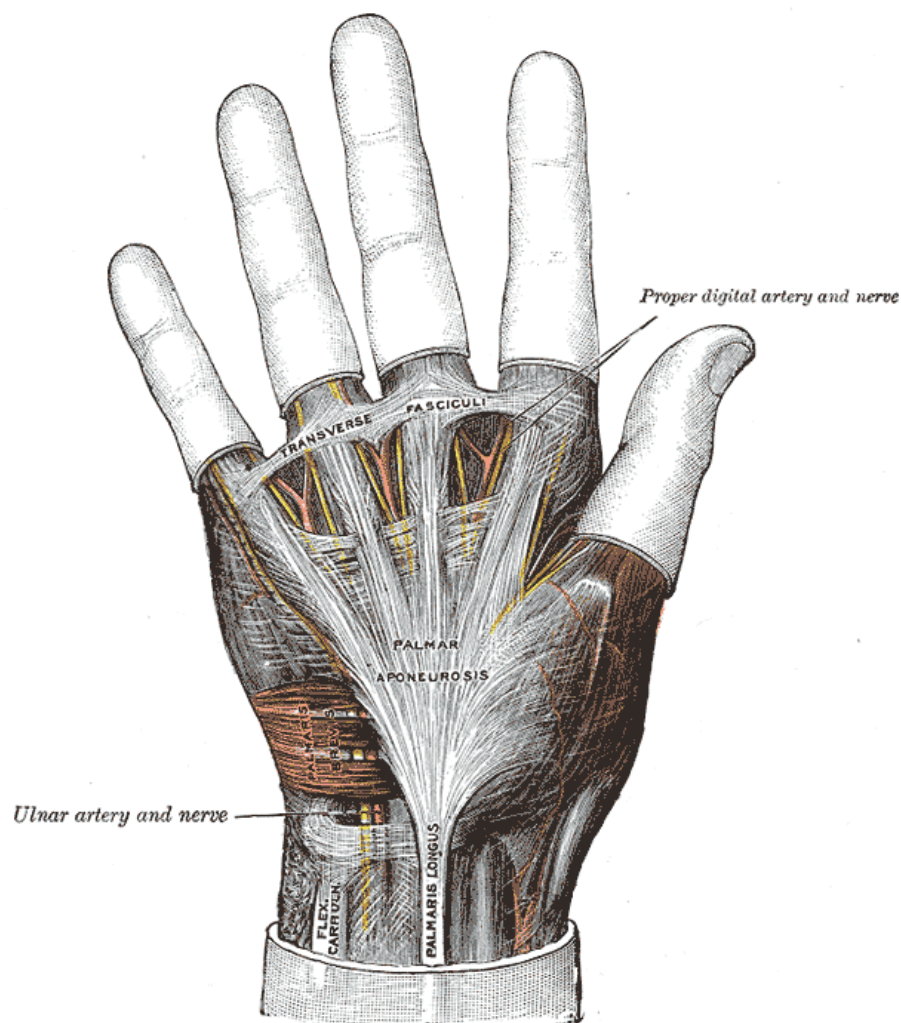


Figure 4 : Depiction of the palmar aponeurosis.

**DIGITAL FLEXOR SHEATH:**

The digital flexor sheath is composed of membranous and pulley component. The pulley portion of the sheath has fibrous tissue bands of annular and cruciform configuration and these are interposed along the synovial sheath in segmental fashion. These maintain the flexor tendons in a constant relationship to the joint axis of motion. There are five annular and three cruciform pulleys. The first annular pulley( A1) begins in the region of the palmar plate of the MCP joint.

Most of these fibers arise from the palmar plate and the remaining fibres arise from the proximal portion of the proximal phalanx. The most usual configuration of the A1 pulley is a single annular pulley, which averages 7.9 mm in width. There is a distinct separation between the A1 and A2 pulleys. This separation is widest on the palmar aspect and ranges from 0.4 to 4.1 mm.

In cases where there is no distinct separation between A1 and A2 pulleys, there is a pronounced thinness to the retinacular tissue, or large triangular openings laterally in the usual site of separation. This allows flexion in the MCP joint without buckling of the pulley complex and thus avoids the impingement of the tendon. The A2 pulley proximal edge is constant in shape with oblique fibers of origin at the proximal and lateral base of the proximal phalanx. In the spaces between the pulleys, synovial outpouching is common. The average width of A2 pulley is 16.8 mm and is thickest in the distal end. The A3 pulley is located at the PIP joint and is attached to the palmar plate.

The A3 pulley average width is 2.8 mm and is present in most cases. The A4 pulley is located on the middle phalanx in the mid-portion and overlaid by oblique fibers to form a cruciate pulley, C3, at the distal end. The C3 pulley is not a separate structure most often. The average length of A4 pulley is 6.7 mm and thickest in its middle aspect. The A5 pulley is quite thin, the average length 4.1 mm, and is attached to the palmar plate at the DIP joint. The synovial sheath ends at the level of the DIP joint, and no pulleys are present beyond this.

( Figure 5)

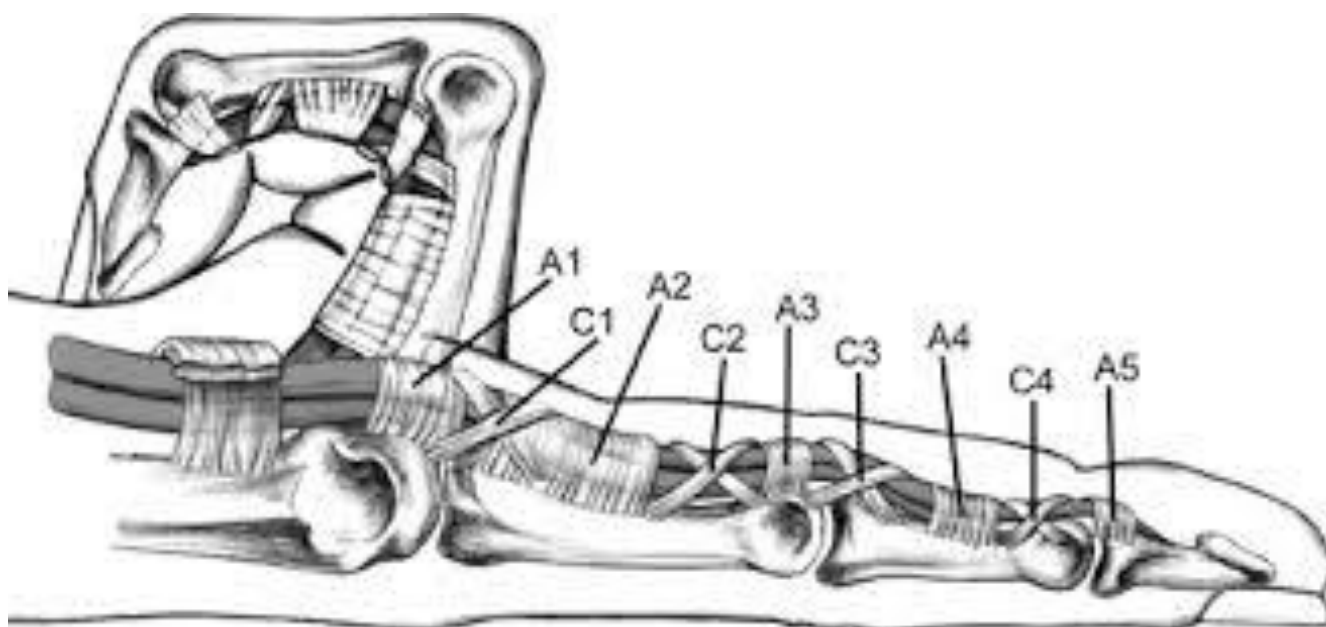


Figure 5 : Illustration of the pulley system.



## FLEXOR ZONES OF THE HAND

The flexor surface is divided into five zones proposed by Verdan. Zone I extends from just distal to FDS insertion to FDP insertion. Zone II (Bunnel's "no man's land") extends between the distal palmar crease and the sublimus tendon. Zone III extends between the transverse carpal ligament and the first annulus pulley it comprises the area of lumbrical origin. Zone IV is covered by transverse carpal ligament the carpal tunnel. Zone V is proximal to carpal tunnel and includes the forearm.(Figure 6)

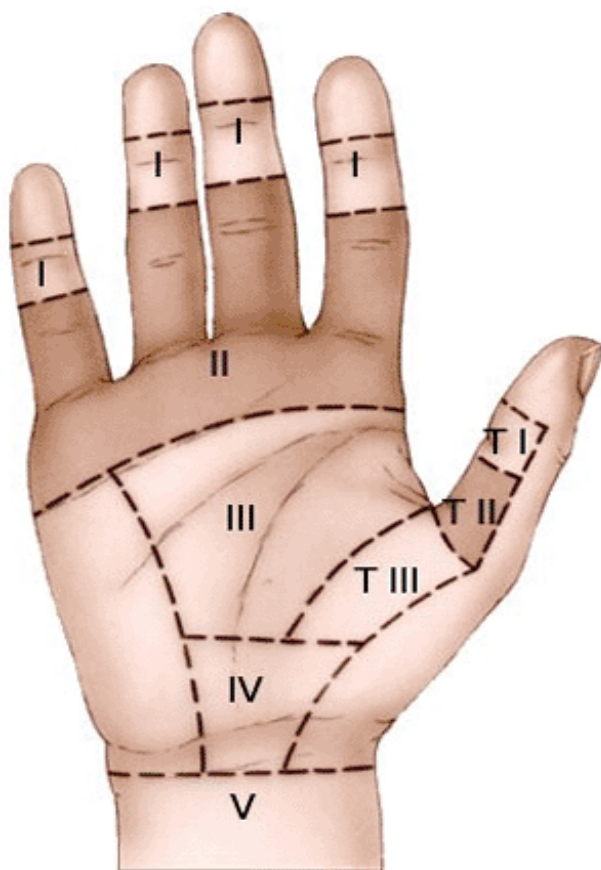


Figure 6 : Depiction of the flexor zones of the hand.

**MODE OF INJURY:**

The common cause of flexor tendon injury is deep cut with knife or broken glass in the wrist, hand or fingers that also cause injury to blood vessels and nerves. The other causes are playing sports like football, rugby and wrestling.

**TYPES OF INJURY:**

There are two types of flexor tendon injury

1. Fully severed tendon- will not be able to flex the fingers
2. Partially severed tendon- will be able to flex the fingers with pain

**SYMPTOMS:**

1. Pain
2. Swelling
3. Inability to flex the finger

**EXAMINATION :**

The assessment of the patient with flexor tendon injuries, begins with assessing the general condition and excluding other injuries, including the use of radiographs. Examination of the neurovascular injury of the hand precedes the evaluation of tendon function. The posture of the hand gives the clue to which flexor tendons are severed . The “finger points the way” toward the injured tendon. Movement of the injured hand is limited due to pain. There is pain when there is associated nerve injury. When both the FDS and FDP are injured the finger stands unusually in hyperextension ( Figure 7)



Figure 7 : Depiction of flexor tendon injury of ring finger

The passive extension of the wrist does not produce the tenodesis effect and flex the fingers when the flexor tendon is injured. If the wrist is flexed there

is greater unopposed hyperextension of the affected fingers. Gentle compression of the forearm causes flexion of the fingers but the injured finger will not flex. If the distal interphalangeal joint can be flexed when the proximal interphalangeal joint is stabilised, the profundus tendon is intact.

To show the transection of the FDS tendon with an intact FDP tendon, the adjacent fingers are held in complete extension, anchoring the FDP in the extended position. This removes the influence of FDP on the proximal interphalangeal joint. When the FDS tendon is injured, while holding the adjacent two fingers in extension it is not possible to flex the interphalangeal joint. (Figure 8). The exception for this evaluation is the index finger FDP because of the independent function.

Lister advocated a technique to evaluate the isolated injury to this tendon, the patient is asked to pinch and pull out a sheet using the thumb and index finger. In an intact finger this function is accomplished by FDS and the distal interphalangeal joint is hyperextended and the FDP is relaxed. If the FDS is injured the distal interphalangeal joint hyperflexes and proximal interphalangeal joint is in extended position<sup>6</sup>. (Figure 9)



Figure 8 : Depiction of examination of the FDS

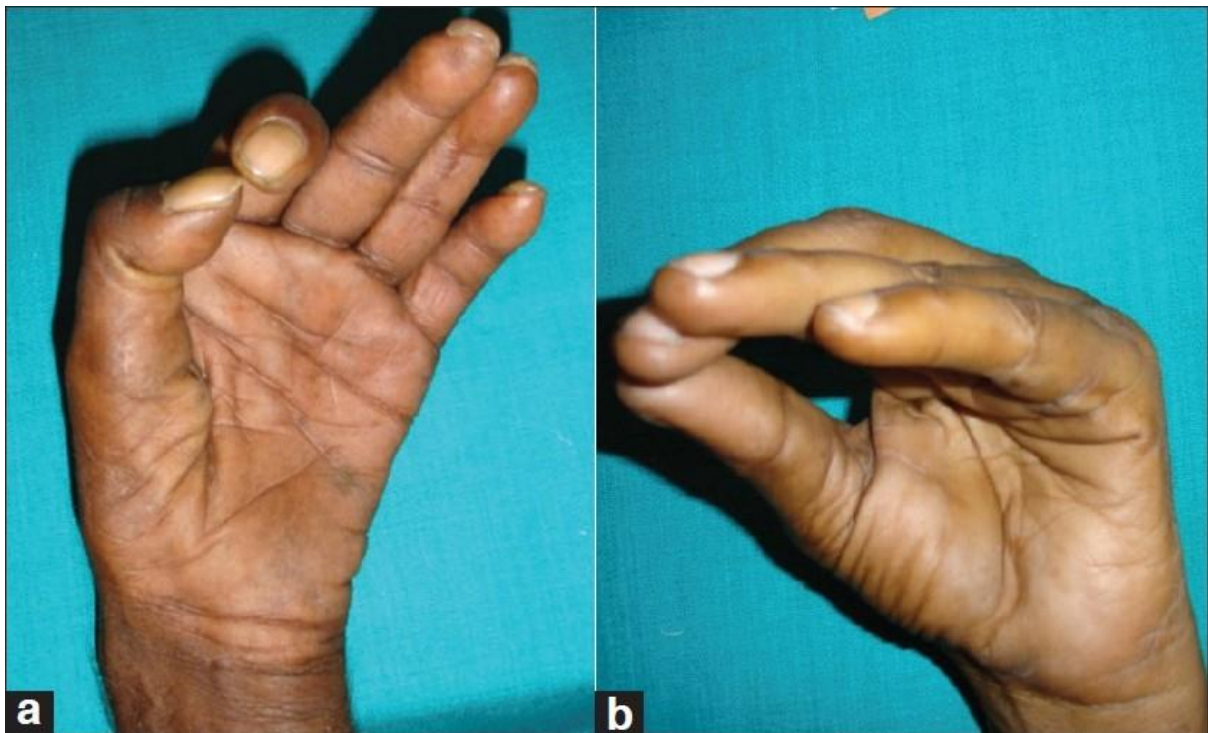


Figure 9 : Lister's technique to evaluate index finger FDS injury

## **FLEXOR TENDON REPAIR TECHNIQUES**

The purpose of the tendon repair is to keep the two ends approximated during healing. The tendon should be handled gently with care while suturing.

Strickland's six characteristics of an tendon repair<sup>6</sup>:

- (1) easy placement of sutures in the tendon,
- (2) smooth juncture of tendon ends,
- (3) secure suture knots,
- (4) prevent tendon vascularity,
- (5) minimal gapping at the repair site, and
- (6) sufficient strength to permit the postoperative motion of the tendon.

### **CORE TENDON SUTURE- COMPONENTS:**

The core suture technique<sup>7</sup> is divided into 3 components namely,

1. longitudinal,
2. transverse, and
3. link component.

The link component helps to bridge a longitudinal and a transverse component or between 2 longitudinal components. The suture techniques have the link and longitudinal components and sometimes have a transverse component (Figure 10). The longitudinal and transverse components are usually

done within the substance of the tendon and the link component is usually placed external to the tendon.

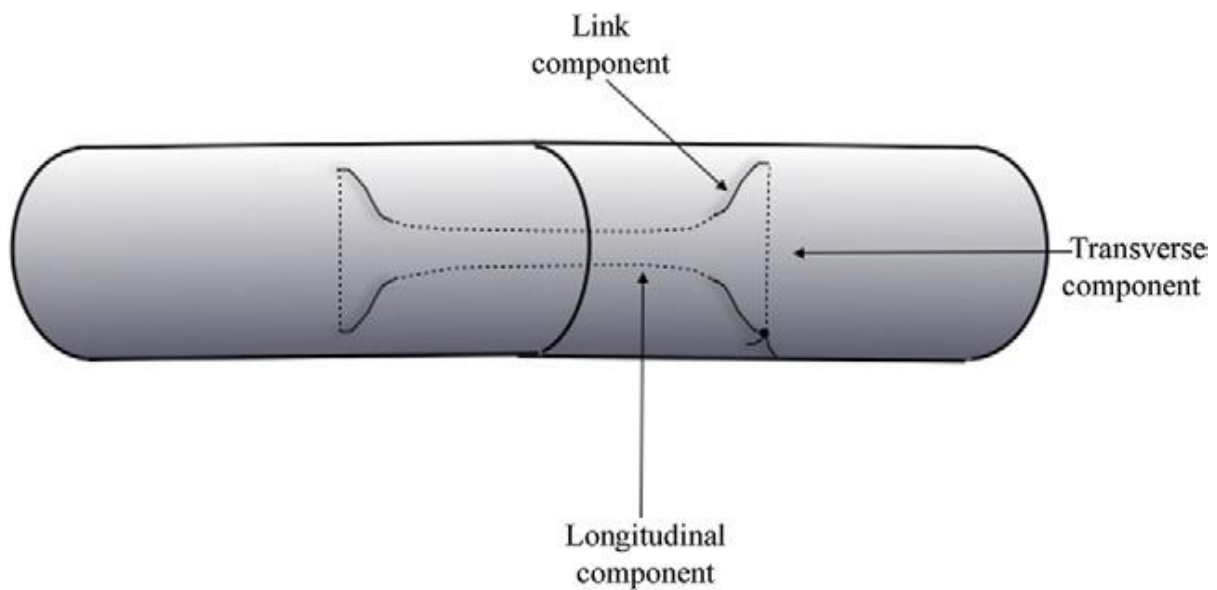


Figure 10 : Depiction of the components of core tendon suture

The transverse and the link components transform the longitudinal force of the suture to a compressive force. This avoids the longitudinal component pulling out. The longitudinal component facilitates the placement of transverse and link components away from the severed tendon ends.

The orientation of the transverse component in relation to the longitudinal component can result in various suture designs. The transverse component is usually placed distal or proximal to the longitudinal component (figure). The transverse component is placed proximal to the longitudinal component. The transverse component may come to lie either superior, inferior, or between the longitudinal components.

The link component may be structured to be an arc, a loop, or a knot. An arc results when the two suture components forming the link, do not cross over each other (a grasping loop). An arc link component does not cover any tendon fibrils. A loop results when the suture components cross over each other thus forming a complete circle (a locking loop) and hence a loop link component holds the tendon fibrils within it. A knot link component results when a loop is secured with a knot. This tendon knot is different from a suture knot that is formed by tying the free ends.

Variations in placing of the link component (arc, loop, or knot) result in a sliding or an anchored suture. A sliding suture allows the suture to glide within the substance of the tendon when force is applied to either of the longitudinal components. An anchored suture does not allow the suture to move independent of the tendon. The link component results in gliding suture and a knot link component results in an anchored suture. The loop link component can result in a gliding or an anchored suture, depending on the complexity of the loop.

A simple loop design will allow the suture to slide and a complex loop design will anchor the suture. The tension is equal when sliding sutures are used and is equally distributed among the different longitudinal strands. In an anchored suture, the longitudinal strands are fixed. Any slack in the suture results in uneven distribution of tension and gapping at the repair. In an anchored suture there is less bunching of the tendon ends when the suture knot is tied.



### THE KESSLER GRASPING SUTURE<sup>7</sup>:

Kessler and Nissim proposed a grasping technique that could withstand the early motion protocol. In a Kessler repair, the suture is anchored to the tendon in all four corners with a knot. These knots prevent the suture from moving within the tendon substance. (Figure 11)

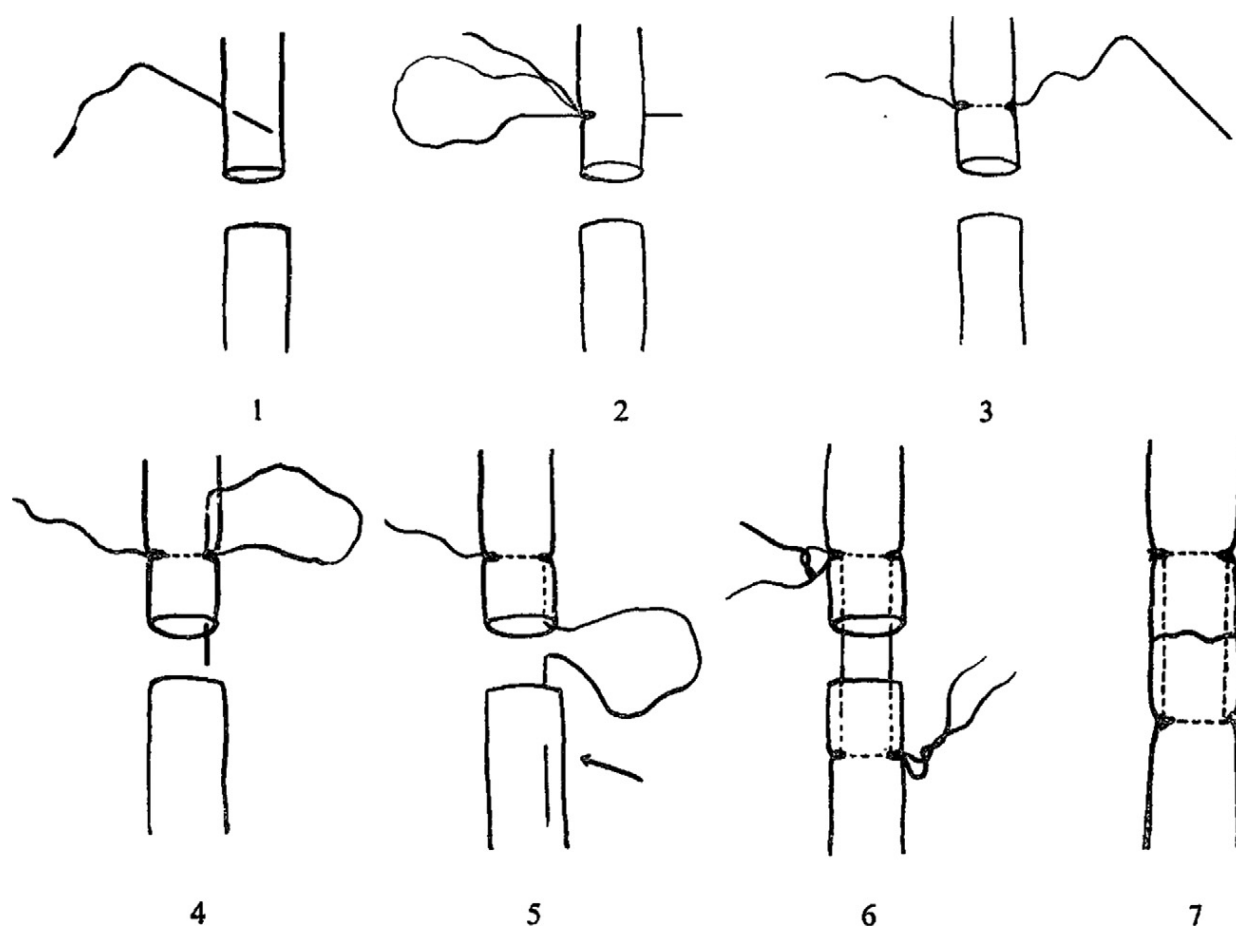
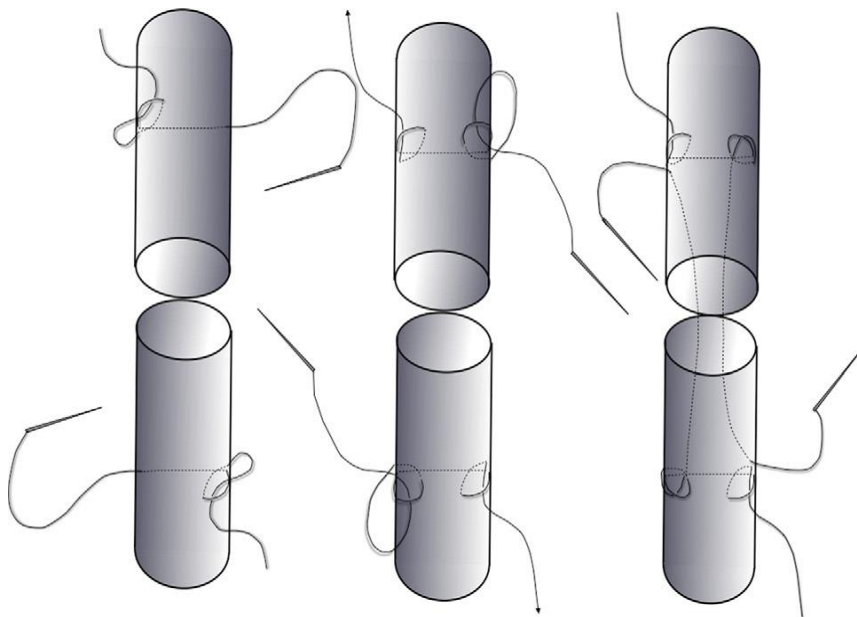
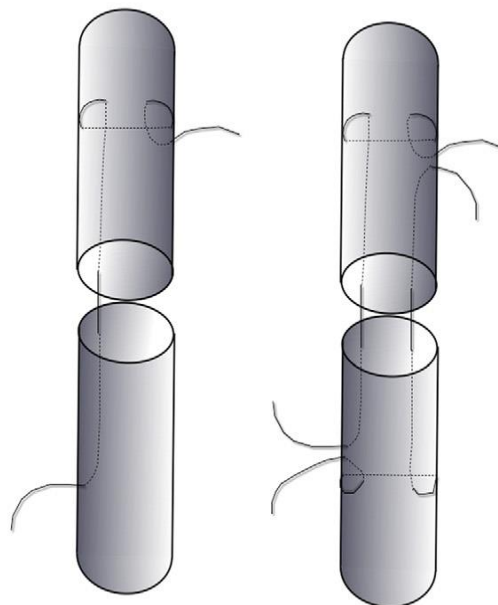


Figure 11; Depiction of the original Kessler Repair.

Urbaniak et al described a modification of Kessler repair( Figure 12) in which he used loops in place of knots at the corner of sutures. In this variant, the suture is not fixed to the tendon and its movement is free within the substance of tendon.



Kessler 'grasping' repair



Urbaniak variant of the Kessler repair

. Figure 12 : Depiction of the Urbaniak variant

## **EVOLUTION OF THE KESSLER GRASPING REPAIR TECHNIQUE**

Nicoladoni described his suture technique<sup>7</sup> with a single strand of suture with intratendinous longitudinal & transverse components linked by an arc link component that resulted in a sliding suture here, the suture knot lies outside the tendon. Kirchmayr's repair was same as Nicoladoni's, except that the transverse component passed between the split ends of the tendon and the far end of longitudinal component. This resulted in a sliding suture with an arc component as link. Bunnell in his description of repair, connected the intratendinous longitudinal and multiple transverse components with an arc link component forming a sliding suture. The Bunnell repair placed the longitudinal component in oblique angle forming figure-of-8.

Mason and Allen's repair technique had longitudinal and transverse components, but it varied from the previous techniques. They used 4 strands of sutures with intratendinous transverse and extratendinous longitudinal components each having 2 parallel transverse components anchored with a tendon knot. The extratendinous longitudinal components were sutured using 2 suture knots placed outside the tendon. The Mason and Allen repair represents the first anchored suture technique.

The Kessler repair was based on the Mason and Allen technique. But it differed from Mason and Allen, in which the longitudinal component was placed intratendinous using 2 suture strands. The link component

comprised of a tendon knot forming an anchored suture. The 2 suture knots outside the tendon are tied diagonally opposite each other.

The variant of the Kessler repair by Urbaniak was similar to the repair by Kirchmayr -sliding suture that used an arc as the link component—except that Urbaniak used 2 sutures that resulting in 2 suture knots outside the tendon. In both the repairs of Urbaniak and Kirchmayr, the transverse component was passed between the cut end of the tendon and the far end of longitudinal component. But no clarification was made regarding the relation of the transverse component to the longitudinal component.

Pennington's repair was the same as Kirchmayr repair, except that the suture knot was buried at tendon junction. This converted the arc component of Kirchmayr and Urbaniak into a loop link. Although the repair by Kirchmayr and Urbaniak and Pennington result in sliding suture, the loop link component of the Pennington repair holds the tendon better than the arc link component of the repair by Kirchmayr and Urban. (Figure 13)

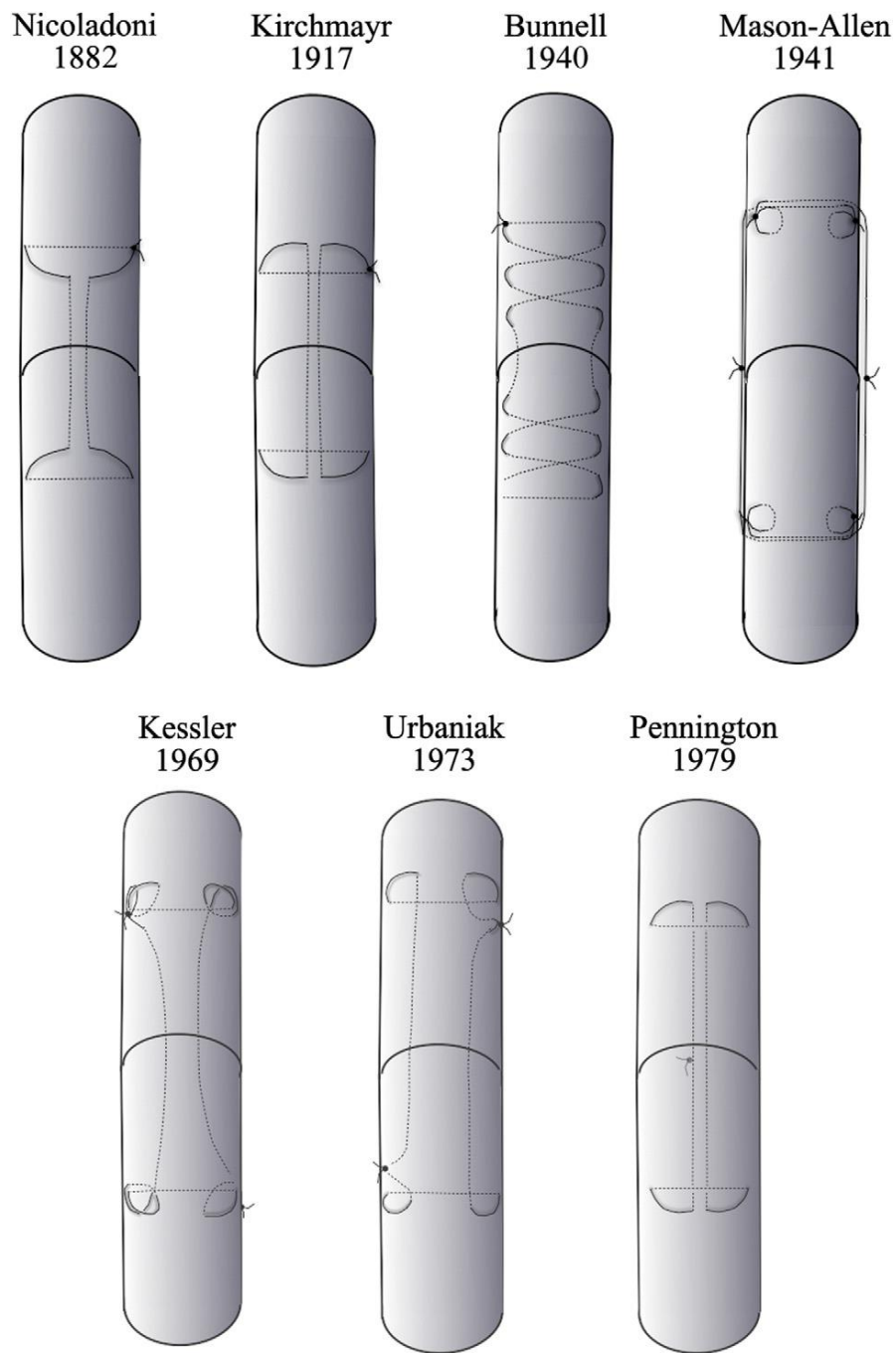


Figure 13: The above figure shows the evolution of two strand repair.

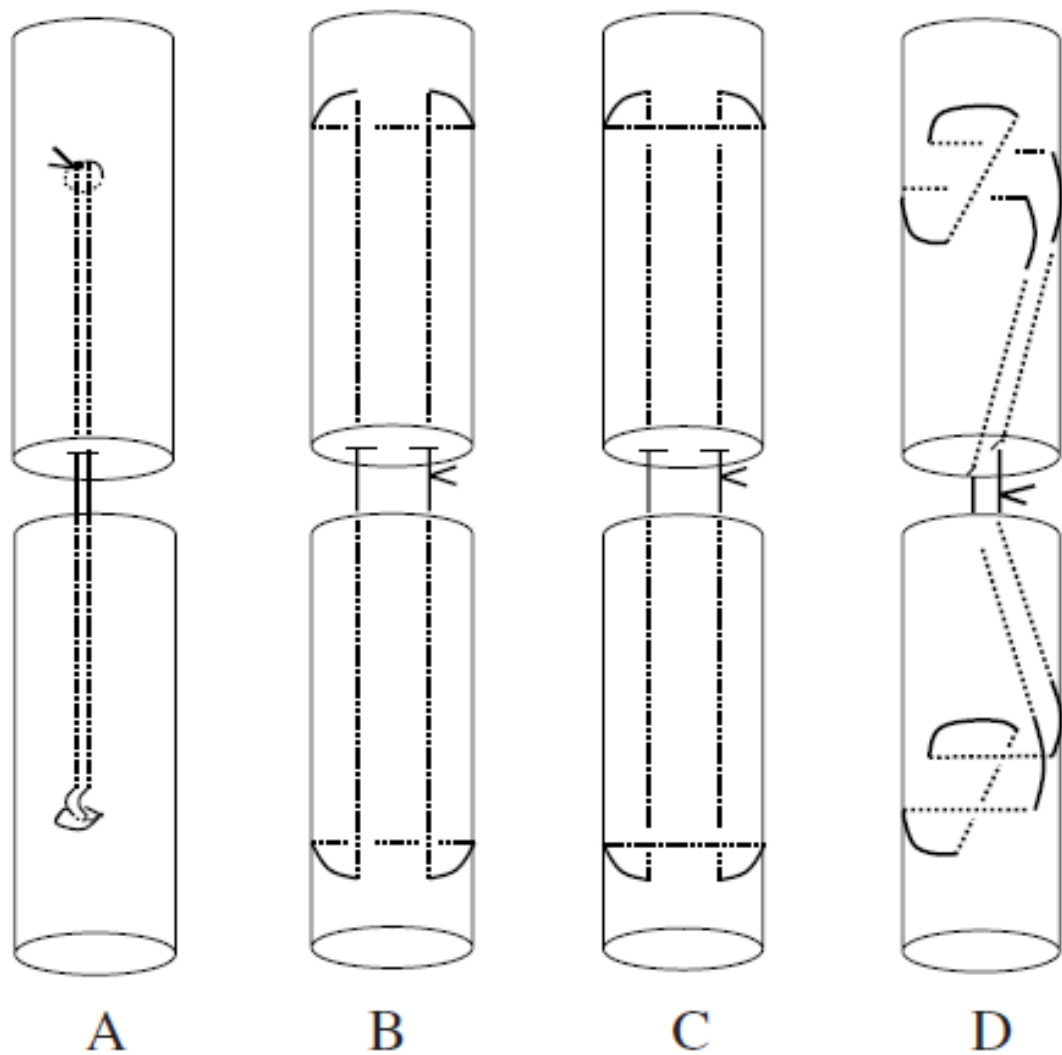


Figure 14 : **Two strand repair techniques**

A) Tsuge

B) Modified grasping Kessler

C) Modified locking Kessler

D) Modified Pennington

The above figure depicts the different two strand repair techniques.

### **THE MCLARNEY REPAIR TECHNIQUE<sup>8</sup> :**

The cruciate repair is done introducing the suture through the slit and advanced longitudinally out the severed tendon end. The needle is placed into the opposing lacerated end and exits on the palmar surface of the proximal segment about 1 cm from the severed edge. The needle is reinserted 1-2 millimeters distal to its exit point on the ulnar surface in a cross-wise fashion directed to exit in the mid substance of the tendon at the severed site.

The needle is reintroduced into the distal part, crossing the tendon till it is brought out 1 cm distal to the severed site on the opposite side. The suture is reinserted a few millimeters distal and palmar to the exit point, again without locking, and directed in a longitudinal fashion out the distal cut end and back into the proximal segment to exit 1 cm proximal to the repair site. The needle is introduced distally and laterally to exit the tendon and directed back across the cut end and the repair.

The suture is brought out the lateral side and reintroduced distally to the longitudinal slit for grasping the tendon edge. The suture exits the first longitudinal slit thus completing the repair. The slack in the suture should be removed even though the nonlocking repair suture allows some final tightening of the repair. The knot is tied and buried in the tendon substance(Figure 15).

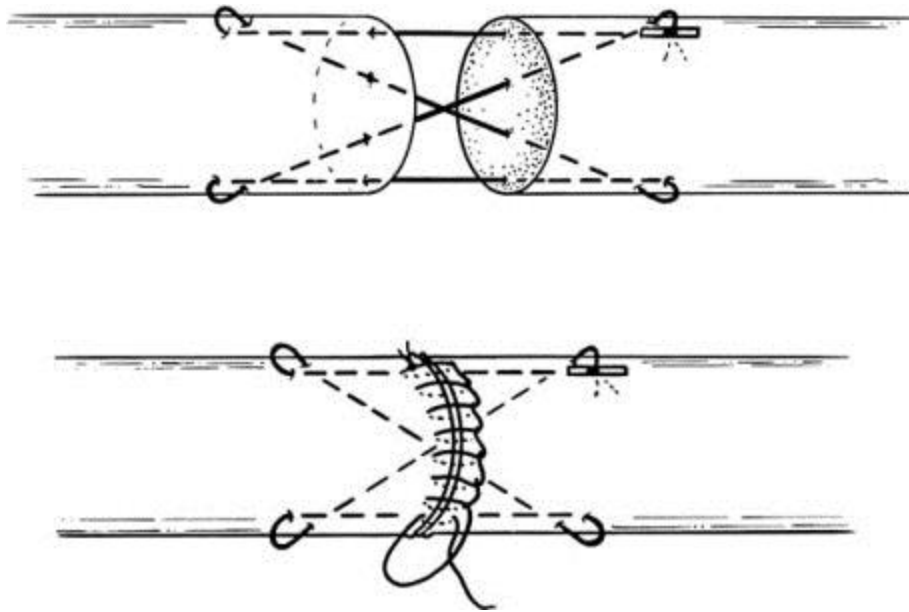


Figure 15 :Depicts the cruciate repair technique .

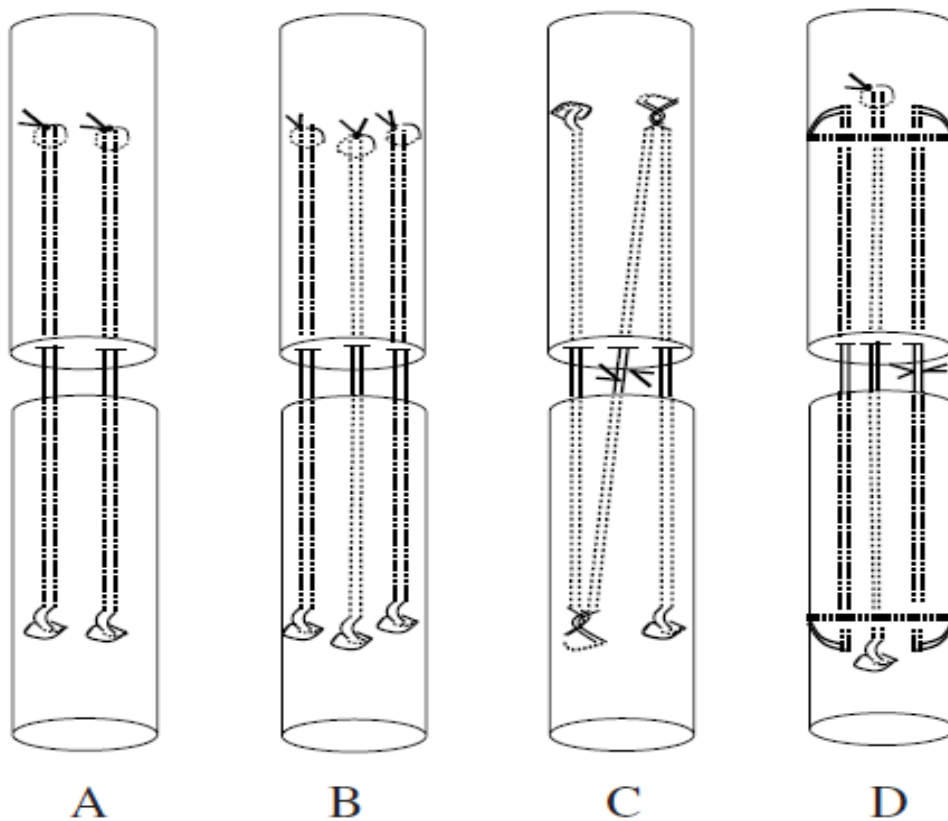


Figure 16 : Multi-strand core suture techniques performed with double stranded suture. A: Double loop suture, B: Triple loop suture, C: Lim, D. Yoshizu. The other different multistrand repair techniques are shown in the pictures below.



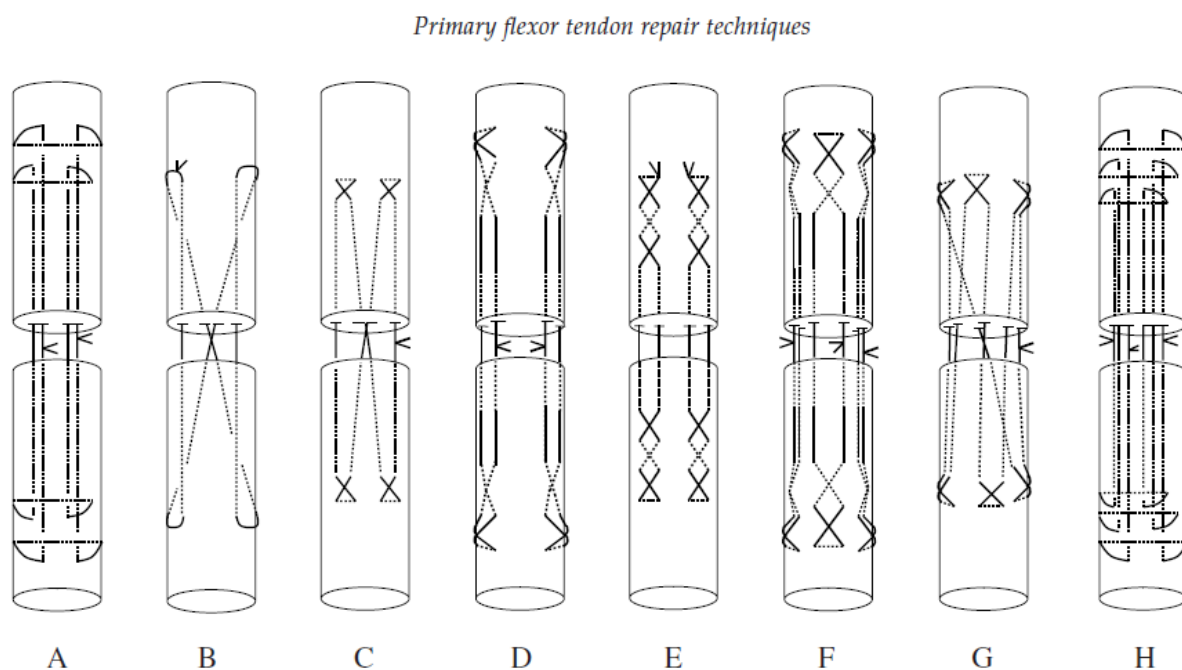


Figure 17 :

**Multi-strand core suture techniques.**

A: Double modified locking Kessler,

B: Cruciate non- locked,

C: Cruciate cross-stitch locked,

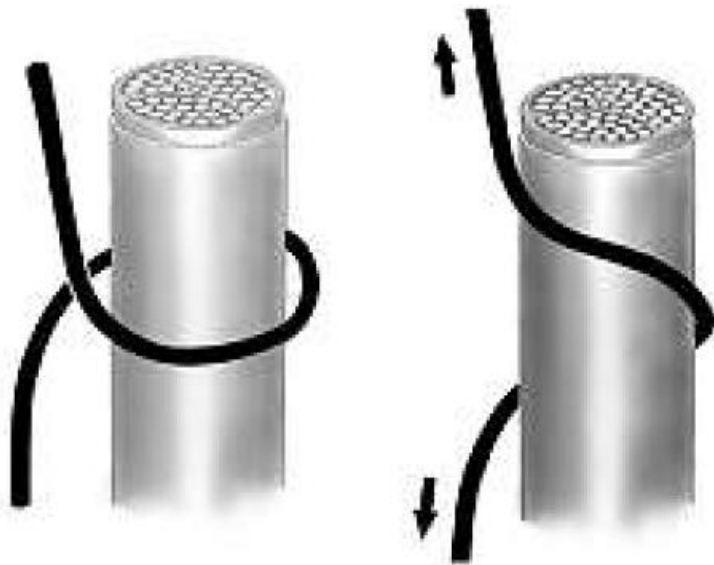
D: 4-strand Savage,

E: Augmented Becker,

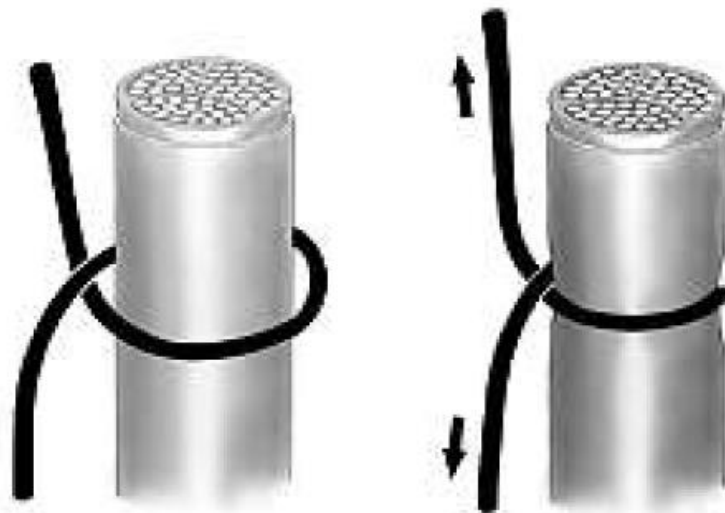
F: 6-strand Savage,

G: Modified Savage,

H: Triple modified Kessler.



*Grasping-loop*



*Locking-loop*

Figure 18: Shows the schematic diagram of grasping and locking loops.

## **AIM OF THE STUDY**

The aim of the study is to analyse the clinical outcomes between the two-strand modified Kessler repair and four-strand cruciate McLarney repair technique following passive motion protocol in adults in terms of

1. Rupture rate
2. Total active motion
3. Grip strength
4. Adhesion

## **REVIEW OF LITERATURE**

### **HISTORY OF FLEXOR TENDON REPAIR :**

The treatment of flexor tendon injury has undergone evolution starting from the first millennium. Galen in the second century described about the repair of nerves and flexor tendons in the forearm and he stopped the repair of these similar structures because it led to uncontrollable convulsions. After 700 years, Avicenna described the direct repair of the tendon, but his teachings were forgotten for centuries. In the last 150 years the direct repair of the tendon has been evolved into an accepted procedure<sup>2</sup>.

In the twentieth century Sterling Bunnell postulated that “firm flexor tunnel does not allow for the necessary swelling of the repair, and the blood supply is squeezed in the tunnel and tendon undergo necrosis”. The subsequent

adhesion formation and poor functional outcome led to declaration of “no man’s land” in the finger<sup>9</sup>. Since then primary tendon graft was done in zone II and repair was abandoned. Pulvertaft stated that it’s not difficult for primary repair in zone II and the real problem was to obtain a freely gliding tendon to restore good function<sup>2</sup>. In 1950s, the other surgeons found that the result of primary grafting in zone II was less satisfactory than repair and reverted back to primary repair. Careful repair technique, improved suture materials and emphasis on postoperative rehabilitation protocol improved the results.<sup>2</sup>

During the last decades there are several articles in the literature about the new techniques of flexor tendon repair and management. This diversity of different techniques suggest that not one method provides consistently acceptable results. One must not dismiss these new techniques even though satisfactory results are achieved by the respective author. The points to be considered in flexor tendon repair: tendon healing, atraumatic repair, suture method, postoperative rehabilitation and evaluation of the results<sup>2</sup>.

## **EVIDENCE ON SURGICAL TREATMENT PLAN:**

The flexor tendon repair is considered as surgical emergency<sup>10</sup>. In Stone and Davidsons retrospective study, 140 patients who presented with open flexor tendon injury were evaluated for postoperative infection. The patients were divided into four groups based on early or late surgery and perioperative antibiotic therapy given or not. There was no significant difference between

these two groups<sup>11</sup>. The direct repair of zone II flexor tendon injury showed good outcomes replaced the primary grafting for these injuries<sup>12</sup>. In an study done on lacerated chicken FDP , the repair done within 24 hours showed superior strength and healing in 60 days compared with the delayed repairs<sup>13</sup>. The delay in repair lead to prolonged inflammation, joint stiffness, adhesion and tendon retraction and will necessitate staged reconstruction.

The epitendinous suture around the tendon tidy up tendon ends, decrease bunching and gap formation and promote smoother gliding. The epitendinous suture adds significant strength to repair<sup>14,15,16</sup>. Kim et al demonstrated that cross stitch technique was stronger than the simple running epitendinous stitch<sup>17</sup>. The depth of penetration of epitendinous stitch one forth the diameter of the tendon is recommended and placing the suture 2mm farther from the repair site increases the strength of repair<sup>18,19</sup>.

The FDP and FDS both should be repaired ideally in zone II lacerations<sup>20,21,22,23</sup>. Taras et al, indicated that the FDS should be repaired whenever possible to improve the range of motion<sup>24</sup>. There also noted that there is decrease in FDS resistance and increase in glide of both FDS and FDP when one of the slips of FDS resected<sup>25</sup>. Paillard et al, demonstrated the benefits of resecting one of the FDS tendon over pulley plasty which decreases the resistance of the remaining FDP tendon<sup>26</sup>.



## EVOLUTION OF FLEXOR TENDON SURGERY

Date	Name	Comments
131 to 201 AD	Galen	Described tendons and nerves are considered single entity & strongly discouraged repairs.
980 to 1037 AD	Avicenna	Described direct tendon repair but teachings forgotten
14 <sup>th</sup> Century	Guy de Chauliac	Defended tenorrhaphy
16 <sup>th</sup> Century	Ambroise Pard Felix Wurtz of Bale and Andre della Croce	Described in details of primary tenorrhaphy Described incidentally on tenorrhaphy
17 <sup>th</sup> Century	Roger of Parma, Roland Lanfranchi of Milan, and William of Salicet Moinichen Landzweerde Meekren Job Baster of Zeland Ganthier, Boevoaert, and Maynaert La Vauguion  Bienaise  Kisner	Advised tenorrhaphy           Described successful cases of tenorrhaphy Detailed successful tendon repair in canine model First demonstrated insensibility of tendon  Three instances of successful tendon repair using silk suture  Successful cases of tenorrhaphy   Performed primary tendon repair, tenorrhaphy for old cases, described scar excision, freshening tendon ends and direct repair Additional skin incision to expose tendon ends,

18 <sup>th</sup> Century	<p>Purman</p> <p>Jean Louis Petit</p> <p>Nuck</p> <p>Samuel Sharp</p> <p>Von Heller</p> <p>Marc Anthony Petit</p>	<p>reapproximated tendon ends by tying silk sutures</p> <p>Preferred direct repairing of tendon ends</p> <p>Army surgeon supported and did 12 successful primary tenorrhaphy</p> <p>Included skin in tendon suture to avoid direct contact with tendon ends</p> <p>Successful division and repair of canine external flexor</p> <p>Regularly sutured divided tendons</p> <p>Conclusively demonstrated insensibility of tendons</p> <p>Successful repair in immediate and late cases of tenorrhaphy using silk</p>
19 <sup>th</sup> Century	<p>Gensoul, Acher, Blandin, and Sanson</p> <p>Rognetta and Mondibre</p> <p>Syme of England</p> <p>Nicoladoni</p> <p>Codivilla of Bologna</p>	<p>Successful cases of tenorrhaphy</p> <p>Against tenorrhaphy inspite of successful repairs</p> <p>Several successful tendon repairs, tenorrhaphy became the accepted procedure</p> <p>Described the techniques of tendon repair</p> <p>Recognised the importance of preserving flexor sheath.</p>
20 <sup>th</sup> Century	<p>Biesalski</p> <p>Lexer of Jena</p> <p>Mayer</p> <p>Kirchmayr of Vienna</p>	<p>Recognised the importance of preserving digital sheath to prevent adhesion</p> <p>1<sup>st</sup> to use Palmaris longus as flexor tendon graft, he emphasized atraumatic suturing and early motion</p> <p>Described the blood supply of tendons, importance of peritenon, tendon sheath motion and tendon transfer.</p> <p>1<sup>st</sup> described the "grasping" method of tendon</p>

	Sterling Bunnell	suturing ( 1917)
	Mason, Shearon & Allen	Reviewed the physiology & anatomy of tendons, achieved excellent results in tendon grafting; described importance of pulley system, atraumatic technique, postoperative rehabilitation(1918, 1922, etc.)
	Graham, Littler, Boyes	He did experiments and clinical work on tendon repair and tendon healing (1932, 1940, 1941, etc.)
	Pulvertaft	Tendon surgery authority in U.S. (1940s and 1950s)
	Siler	
	Verdan	Tendon surgery authority in U.K.; advocated the objective evaluation of postoperative function (1940s and 1950s)
	Kelly	Reported on primary tenorrhaphy (1950)
	Young, Harmon	Reverted back to primary repair of flexor tendons (1950s)
	Kleinert, et al	Reported on primary tendon repair (1958)
	Bruner	Elastic traction; 5-0 Running chromic catgut suture (1960)
	Peacock, Potenza, Matthews, and Richards	Did primary repair in Zone II; used modified Bunnell core suture and running epitendon suture; described the active protected postoperative mobilization using elastic traction (1950s, 1960s)
	Hunter	Anterior zigzag digital incision for flexor tendon surgery (1960s) Further understanding of flexor tendon physiology (1960s, 1970s)

	<p>Kessler, Tajima, and Tsuge</p> <p>Duran and Houser</p> <p>Lundborg</p> <p>Matev, et al.</p> <p>Lister</p> <p>Manske</p>	<p>Used artificial tendons and gliding artificial implant( striper) for tendon sheath reconstruction; described the anatomy of flexor tendons pulley, vincular, synovial, and vascular structures. (1960s, 1970s, 1980s)</p> <p>Described methods of intratendinous suturing; techniques remain popular today (1970s)</p> <p>Controlled <i>passive</i> motion postoperatively (1970s)</p> <p>Role of tendon sheath and synovium in healing and tendon nutrition</p> <p>Delayed primary repair of flexor tendons cut in digital theca (1980)</p> <p>Described the importance of sheath closure in primary tendon repair (1980s)</p> <p>Flexor tendon nutrition (1980s)</p>

## **SUTURE MATERIAL :**

The suture material used for the tendon repair should be nonreactive, small caliber, and strong, and should have good handling characteristics. A variety of suture materials have been used for tendon repair<sup>27,28</sup>. The different suture materials are Ticron, Nylon, Prolene, Mersilene, Stainless steel wire and Fiberwire.

Vizesi et al studied both the static and the viscoelastic mechanical properties of various suture materials. They tested Prolene, Ethilon and Ticron with respect to gap formation in physiological buffered solution at both room and body temperature and concluded that Ticron is the most suitable suture compared with Prolene and Ethilon<sup>29</sup>. Lawrence and Davis, studied the mechanical properties of 5 nonabsorbable suture material and found that suture material strongly influence the biomechanical properties of multistrand tendon repairs. They concluded that Fiberwire and stainless steel are the most suitable suture materials and nylon is the least<sup>30</sup>. Haimovici et al, evaluated the tensile strength of flexor tendon repair using the fiberwire, strongest suture material and locking configuration suture technique using two- and four- strand repair to see what factor plays the important role in tendon repair. They concluded that suture strand configuration rather than strict number of strands or strength of suture material yielded the maximum strength with reduced gap at repair site<sup>31</sup>.

## **SUTURE TECHNIQUE:**

The characteristics of the repair technique alter the strength of the coapted tendon. The suture material, the number of strands, the knot location, the position of strand within the repair site, the type of purchase on the proximal and distal ends, and the use of locking and nonlocking sutures offer advantages and disadvantages to repair strength and outcome.

The modified Kessler, a two strand technique has been used for many years because of its technical simplicity. But the recent studies demonstrates that the strength of the repair is directly related to the number of strands crossing the repair site.

McLarney et al in 1999 developed and tested in vitro cruciate flexor tendon suture technique and compared with modified Kessler, Strickland and modified 4 strand savage repair. Each repair was tested with slow test machine (tensile testing machine) and displacement control of 2mm/s. They concluded cruciate suture technique found to be twice as strong compared with other three techniques. The technique was significantly faster to perform than the Savage or Stricklands repair and was comparable in time with 2 stranded Kessler repair<sup>8</sup>.

Timothy Thurman et al in 1998 compared gliding resistance, gap formation and ultimate strength of the 2-, 4-, and 6-strand repair techniques in cadaver model of zone II flexor tendon. They tested the strength of the suture with pneumatic cylinders. They

determined the force required to flex the proximal interphalangeal joint to 90 degree. The 2- and 4- strand suture was done with suture interlock technique. The dorsal side and palmar side of the tendon was repaired after core suture placement. After repair each hand was mounted on frame and cycled 1000 times. The resulting gap between the repaired tendon was measured and each was loaded to failure in tension. All tendon repairs showed a small , but there was no significant increase in gliding resistance. The tensile strength of 6 strand repair was significantly greater than the 4 strand or 2 strand repair<sup>32</sup>.

Dinopoulos et al in 2000 evaluated the resistance of a 4-strand and an 8- strand suture technique to gap formation during tensile testing. They had hypothesis that the 8-strand repair would sustain higher force levels at the onset of 1-and 3-mm gaps than the 4-strand repair. They transected twenty two canine flexor tendon, were repaired and tested to failure after 10 days of in vivo healing. The test was recorded with video playback system for assessment of gap formation. The 8 strand repair sustained 80% higher force at a gap of 1mm than the 4-strand repairs. ( average force 70vs 39N), but the force sustained at a gap of 3-mm did not differ between the groups.( 35N for both the groups). For both 4-strand and 8-strand repair, a 1-mm gap occurred near the point of ultimate force while a 3-mm gap occurred after the ultimate force. They concluded that the 8- strand repair is significantly more resistant to initial gapping during ex vivo tensile testing than the 4-strand repair but that the two repairs are equally susceptible to rupture if a gap of 3-mm or greater forms<sup>33</sup>.

Barrie KA et al in 2000 did a biomechanical analysis of multistrand flexor tendon repair using an In situ model. The test model was used to evaluate the performance of zone II flexor tendon repair and to compare the biomechanical properties of 4-strand repairs with 2- and 6-strand repairs. Fifty digits from human cadaveric hands were mounted in a tensile testing machine. Intratendinous metallic markers were placed to determine the gap formation by fluoroscopy during tensile testing. Three 4-strand repairs were compared with the 2-strand Kessler and the 6-strand Savage repairs. The ultimate tensile strength, load at 2, 3, and 4-mm gap formation, and flexion were determined.

They found that the tensile strength of the 6-strand repair was significantly greater than that of the 2- or 4-strand repairs and tensile strength of all 4-strand repairs was significantly greater than the 2-strand repair. The 6-strand repair and the 2 cruciate repairs demonstrated a statistically increased resistance to gap formation compared with the 2-strand Kessler repair. They concluded that 4- and 6- strand repairs have adequate strength to withstand the early active motion protocols<sup>34</sup>.

Seradge H et al in 2000 designed a new technique, Oklahoma repair technique and compared with modified Kessler with epitendon suture on 40 FDP tendons in cadaver. They concluded that addition of epitendon repair increased the tensile strength of repair regardless of the core suture technique<sup>35</sup>.



A.M. Navali et al in 2008 compared the active ranges of finger motion and rupture rates of two-strand and four-strand repairs in zone 2 flexor tendon lacerations in young children. 32 Flexor tendon lacerations in zone 2 were evaluated. The injured tendon was randomly repaired with either 2 strand or four strand modified Strickland techniques. After a mean follow up period of 11 months, the mean total active motion of interphalangeal joint was 156 degree in the two strand and 158 degree in the four strand group. There was no rupture of four strand group but one two strand ruptured within 3 weeks. In conclusion there was no significant difference in the active motion statistically<sup>36</sup>.

### **Strength of repair is directly related to the number of strands:**

Wu et al did biomechanical comparisons of four stranded tendon repairs with double stranded sutures and effects of different locks and suture geometry. Forty eight pigs flexor tendons were repaired with four four-strand technique, a cross lock four-strand repair, a U shape repair with circle loop, a modified Kessler repair with Pennington locks (longitudinal repair located more centrally) and another modified Kessler ( longitudinal sutures located laterally). The tendons were loaded to tensile testing machine and were subjected to load-to-failure test. The two Kessler repair had 35% lower 2mm gap force and 15% decrease in ultimate strength compared with other two repairs. The study findings indicate that for a four-strand repair, different locking junctions may generate difference in overall strength and an ideal repair is created by

incorporation of optimal locks to maximize strength. They concluded that four strand cross lock repair and U shape repair have more strength than the four-strand Kessler repair<sup>37</sup>.

Mohammed M analysed six-strand technique for zone II flexor tendon repair in children less than 2 years of age<sup>38</sup>. They treated 12 children, less than 2 years, with 12 injured fingers over a period of 10 years. A profundus only repair technique was done using three separate 'figure of eight' of core sutures and continuous epitendinous suture. The hand was immobilised for 3.5 weeks and then physiotherapy was initiated. There was no ruptures and total active motion was excellent in nine and good in three. They concluded that six-strand technique is an alternative technique for zone II flexor tendon injury in children but the bulky repair site requires profundus only repair<sup>38</sup>.

Peltz et al studied influence of locking stitch size in a four strand cross locked cruciate flexor tendon repair. They harvested 22 deep flexor tendons from adult pig and cut at a standard point. They performed a 4-strand cross-locked cruciate repair using 3-0 braided polyester either 4-mm cross locks or 2-mm cross locks and were loaded to failure after repair. They concluded that 4-strand cross lock cruciate with cross locks of either 2-mm or 4-mm provide high tensile strength and resistant to pullout<sup>39</sup>.

Al-Qattan MM et al did a biomechanical study of flexor tendon repair in zone II comparing combined grasping and locking suture with their grasping and locking components. They used sheep profundus tendon and repaired with six strand grasping technique, four-strand locked technique and 10-strand repair using both figure of eight and cruciate repairs. The combined repair was found to be stronger when loaded to failure<sup>40</sup>.

Tang JB et al assessed the length of the core suture purchase affecting the repair of transversely cut tendons using 2-strand Modified Kessler and 4-strand circle locking method. Fifty eight pig flexor tendons were repaired with 2-strand grasping repair technique with core purchase in the tendon ranging from 0.4 to 1.2cm. Sixteen tendons were repaired with four-strand circle-locking repair with the core purchase ranging from 0.4 to 1.0cm. The tendons were load to failure in tensile testing machine. The ultimate strength of the 2-strand repair increased from 0.4 to 0.7, 1.0 and 1.2cm but the strength remained constant from 0.7 to 1.2cm. The 4-strand circle locking suture with 1.0cm purchase the strength was greater compared with 0.4cm purchase. They concluded that both in 2-strand and 4-strand circle locking suture the length of core purchase increases the ultimate strength and gap formation. They determined that the optimal length of purchase is 0.7 to 1.0cm and increase in length more than this does not increase the strength<sup>41</sup>.

Schuind et al in 1992 defined the flexor tendon forces *invivo*. They developed S-shaped force transducers to measure the forces along the intact tendon. The transducers were introduced to flexor pollicis longus, flexor digitorum superficialis and profundus tendons of the index finger in five patients operated for carpal tunnel syndrome. The tendon forces generated during the wrist and fingers passive and active motion were recorded.

During passive mobilization of the wrist tendon forces were in the range of 0.1 to 0.6 kgf. During passive mobilization of the fingers tendon forces were up to 0.9 kgf . Tendon forces were up to 3.5 kgf during active unresisted finger motion. Tendon forces were up to 12.0 kgf during tip pinch, with a mean applied pinch force of 3.5 kgf. They concluded that these results have potential application in determining the amount of force that a tendon repair should withstand during passive and active postsurgical mobilizations<sup>42</sup>.

Strickland's data in 1993 illustrate that a tendon repair above a four-strand repair will permit active motion protocol postsurgical. His compilation of force- to- rupture data is illustrated in Figure 19.

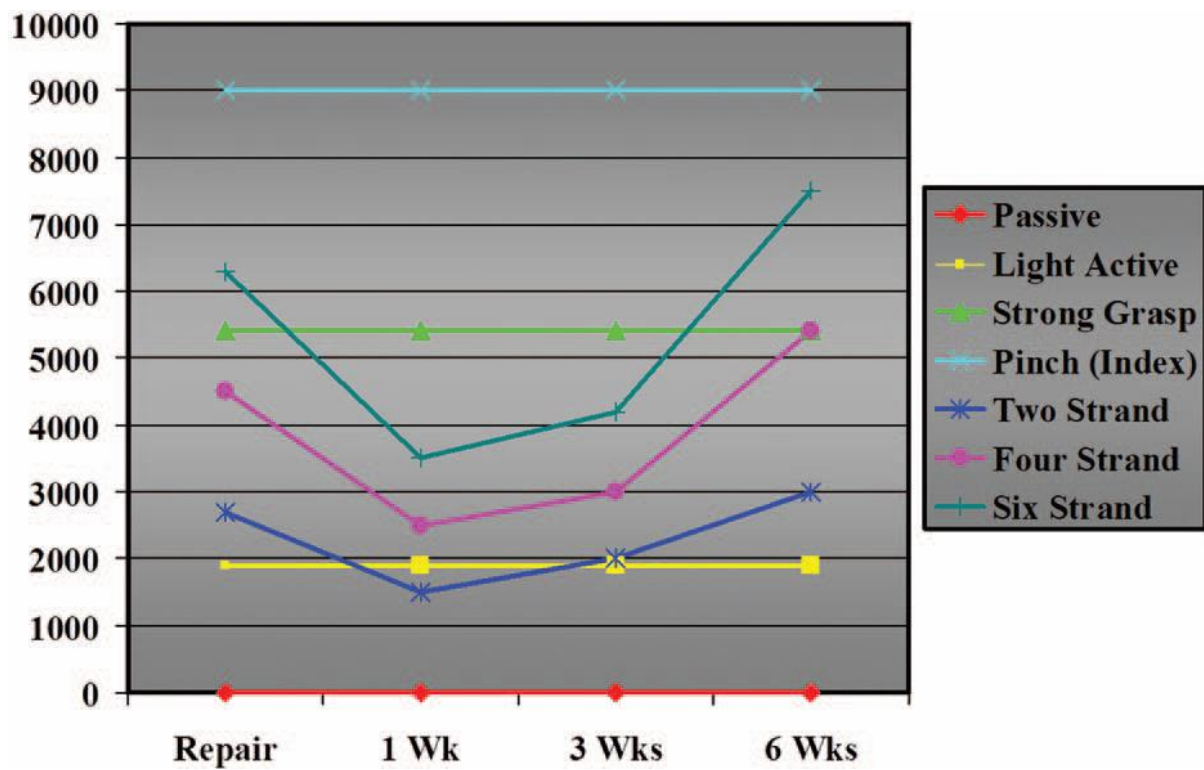


Figure 19: The forces on the tendon repair generated by various activities relative to the strand strengths.

## **REHABILITATION PROTOCOLS:**

The three basic protocols for flexor tendon repairs are

1. Immobilization protocol
2. controlled passive motion protocol and
3. early active motion protocol.

Immobilization protocol was first advocated by Bunnel evolved to passive motion protocols, which have evolved into early active motion protocols. All three programs have their roll in hand rehabilitation.

### **1. IMMOBILIZATION PROGRAM**

Using complete immobilization postoperatively is the conservative approach to rehabilitation. The immobilization program is indicated for the following reasons: children and adults who are unable to comprehend and follow a mobilization protocol, associated injuries to the adjacent structures, such as fracture, and health conditions that affect tissue healing, such as rheumatoid arthritis<sup>43</sup>. Collins and Schwarze developed an early progressive resistance program following immobilization<sup>44</sup>. The dorsal blocking cast positions the wrist and metacarpophalangeal (MCP) joints in flexion and the

interphalangeal(IP) joints in full extension. The cast is removed after 3–4 weeks and replaced by a dorsal blocking splint. The hand mobilised passively with the wrist held in 10 degree of extension and gentle differential tendon gliding exercises.(Figure 20)

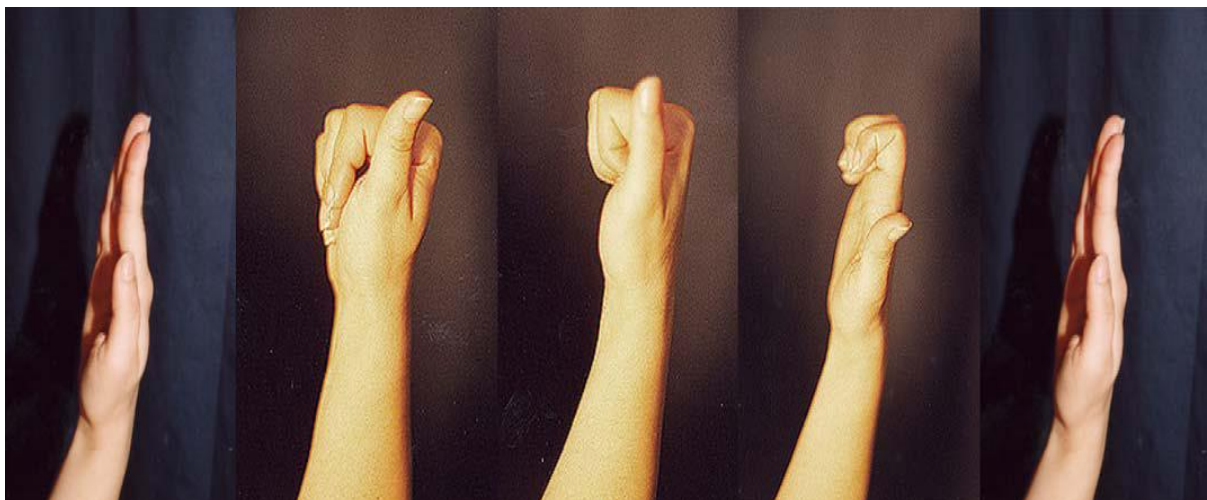


Figure 20: Differential gliding exercise

After 4 to 6 weeks the dorsal protective splint is discontinued during the day and advice to wear only in night and outdoor for protection. Gentle active wrist and digital extension begins, with blocking and fisting exercises. At this phase, if extrinsic flexor tightness is noted, a forearm based splint holding the wrist and digits in extension is worn at night. Significant resistive exercise begins at 6–8

weeks. Timing and load intensity of the resistive exercise depends on the severity of adhesion formation<sup>43</sup>.

Table A :

Immobilization program

0-3weeks	3-4 weeks	4-6 weeks	6-8 weeks
Cast in wrist and MCP joint flexion and IP joint full extension	Dorsal protective splint with wrist in neutral Hourly: 10 repetitions of passive digital flexion and extension with wrist at 10 degree extension Hourly: 10 repetitions of active tendon gliding exercises	Dorsal blocking splint discontinued Gentle blocking exercises initiated 10 repetitions, 4-6 times daily added to passive flexion and tendon gliding	Gentle resistive exercise begin and progressed gradually



## **2.CONTROLLED MOTION PROTOCOL:**

Because of improvements in suture techniques, a trend developed in tendon rehabilitation from immobilization to early controlled motion protocols. Studies have shown that early controlled forces applied to the healing tissues improve recovery of tensile strength, improve tendon excursion, decrease adhesions, and promote intrinsic healing<sup>45,46,47</sup>.

### **KLEINERT PROGRAM:**

In 1960, Kleinert introduced controlled passive motion protocol using dorsal protective splint with elastic traction from finger nail to volar forearm. The elastic flexion pull acts as the repaired flexor tendon unit without muscle contraction. Active extension of the digit is performed within the limits of the dorsal blocking splint. Because of flexion contractures at the proximal interphalangeal joint and loss of active distal interphalangeal motion, two modifications became standard: a palmar pulley was added to improve DIP flexion, and at night the elastic traction is detached and the fingers strapped into extension within the splint to prevent PIP joint flexion contractures. The protocol is outlined in Table B<sup>43</sup>.

### Kleinert program

0 to 3 days	0 to 4 weeks	4 to 6 weeks	6 to 8 weeks
Dorsal protective splint with wrist, MCP joint in flexion and IP joint in full extension. Elastic traction from finger nail to volar forearm through palmar pulley.  Velcro strap to release finger traction in night time	Hourly extension of fingers within the limits of the splint and flexion with elastic traction only.  Wound and scar care	Dorsal protective splint discontinued and wrist cuff, elastic traction given  Night protective splint to prevent contracture  Active wrist and gentle fisting exercise initiated  At six weeks blocking exercise begin	Progressive resistive exercise begin

Table B: Kleinert passive motion protocol.

### DURAN PROGRAM :

In the 1970s Duran and Houser introduced a controlled passive motion protocol using dorsal protective splint without elastic traction. The program was designed so that 3–5 mm of tendon glide would prevent restrictive adhesion in zone II. Passive dorsal and proximal interphalangeal joints extension and MCP joint flexion was found to glide the FDP away from the FDS suture sites.

Passive proximal interphalangeal joint extension with MCP and DIP flexed

glides both tendons away from the injury site. Duran protocol is outlined in the Table C.(43)

0 to 3days	0 to 4.5 weeks	4.5 to 5.5weeks	5.5 weeks	7.5 weeks
Dorsal Protective splint applied with wrist in 20 degree flexion, MCP joints in 50 degree flexion, IP joints full extension	Hourly exercise within splint  10 repetitions passive DIP extension with PIP and MCP flexion  10 repetitions passive PIP extension with MCP and DIP joint flexion	Splint replaced with wrist cuff and elastic flexion traction from fingernail to cuff  Continue active Extension and passive flexion	Wrist cuff discontinued  Blocking and fisting exercises initiated	Light resistive exercises with putty  Splinting to correct extrinsic flexor tightness.

Table C: Duran passive motion protocol

### **3.EARLY ACTIVE MOTION PROTOCOL**

In the late 1980s and early 1990s early active motion protocols developed in response to clinical studies that demonstrate beneficial effects of early (as early as 24 hours postoperative) active motion . Early active motion protocols depend on strong repair techniques. The tensile strength of the repair should be greater than the force applied during rehabilitation to prevent gapping or rupture. Combined metacarpophalangeal flexion and wrist extension has found to reduce the tension on the repaired site and to allow the most differential excursion between FDS and FDP on a repaired tendon. Studies done in cadaver using tenodesis motion showed the following tendon excursions: FDS, 15.2 mm; FDP, 19.8 mm; and FDS-P, 4.6 mm.

Strickland introduced an active motion protocol for a four-strand repair with epitendinous suture Table D. This protocol incorporates the tenodesis motion within a hinged splint which allows 30 degree wrist extension. Good patient motivation, comprehension, controlled edema and wound complications are required.(43)

Table D: Strickland/Indiana hand protocol

0-3days	0-4weeks	4 weeks	5 weeks	6 weeks	8 weeks	14 weeks
<p>Dorsal blocking splint with wrist in 20 degree flexion, MCP joints in 50degree flexion</p> <p>Tenodesis splint allowing 30 degree wrist extension and full wrist flexion, Maintaining MCP joints in 50degree flexion</p>	<p>Duran passive motion done 15 times every 2hours</p> <p>Tenodesis exercises within splint 15 times every 2 hours</p>	<p>Dorsal blocking splint discontinued during exercise but continued for protection</p> <p>Tenodesis exercises to Continue</p> <p>Instruction to avoid simultaneous wrist &amp; finger extension</p>	<p>Active IP flexion with MCP extension followed by full digits extension</p>	<p>Blocking exercises begin if active tip to distal palmar crease is &gt; 3 cm</p> <p>Passive extension begin at 7 weeks</p>	<p>Progressive resistive exercises started</p>	<p>Unrestricted use</p>

## **MATERIALS AND METHODS**

The proposed study was designed and conducted in a rational and ethical manner as detailed below.

### **Study design:**

Double blinded Randomised controlled trial on two- strand repair(Modified Kessler) versus four-strand repair (McLarney) of flexor tendon injury of hand in adult population.

### **Mode of blinding:**

The patient and the observer( hand physiotherapist ) are blinded in the study.

### **Place of study :**

Dr. Paul Brand Centre for Hand and Leprosy reconstruction and Peripheral nerve surgery, Christian Medical College and Hospital, Vellore.

Time period of observation:

1<sup>st</sup> of November 2013 to 30<sup>th</sup> September 2014. The patients were observed at the end of 6 months.

### **Sample size:**

Using the literature evidence, sample size was calculated to 66 tendons, 33 in each arm

$$n=2(Z_{1-\alpha/2}+Z_{1-\beta})^2 \cdot \sigma^2 \delta^2$$

$$\delta^2 = \text{effect size} = \text{mean}_1 - \text{mean}_2 = 33.9 - 43.0$$

$\sigma$ =standard deviation of 2 groups=11.2

$Z_{1-\alpha/2}$ =1.96 for 5% error

$Z_{1-\beta/2}$ =0.84 for 80% power

calculated by using Stata software

A sample size of 66 (33 in each arm) is needed to detect a mean difference of (33.9-43= 9.1) with a power of 80% and error of 5%.

A total of 10 patients were enrolled for the study. In them 58 injured tendons were repaired. Due to constraints in the follow up time, 7 patients with 38 injured tendons could only complete the 6 months postop followup. Out of that one patient with 8 tendon injury was excluded from the study since he did not follow the passive motion protocol exercise which resulted in adhesion and flexion contracture. Hence the final observed sample turned out to be 30 injured tendons with 16 tendons in two-strand group and 14 tendons in four-strand repair group.

#### **Inclusion criteria :**

1. 16 to 50 years age group of both sex
2. Acute trauma
3. Isolated flexor tendon injury from Zone 2 to Zone5
4. Repair done by expertise hand surgeon



**Exclusion criteria :**

1. Age less than 16 and more than 50 years
2. Chronic injury
3. Associated extensor tendon injury
4. Associated with fractures
5. Bilateral hand injury
6. Patients who did not follow the passive motion protocol
7. Patients who develop contractures in the postop period

**Materials used :**

1. 3-0 ethibond material for core suturing
2. 6-0 nylon for epitenon suturing
3. Above elbow cast(Figure 21)
4. Elastic traction from finger nails through a palmar pulley to the volar forearm (Figure 22)
5. Night productive splint after 4 weeks postop for prventing contractures



Figure 21 : Depiction of above elbow cast



Figure 22 : Depiction of the elastic traction from the finger nails to the volar forearm through the palmar pulley

### Assessing tools:

1. Goniometer- to check the total active motion of the proximal and distal interphalangeal joints of fingers.

2. Kern hand grip dynamometer- to check the total grip strength of the repaired tendons postop

3. Proximal and distal interphalangeal joint extension blocks(Figure 23)- to evaluate the strength of the individual tendons repaired

4. ASSH (American Society for Surgery of Hand) Score – to evaluate the range of total active motion of the repaired tendons.

#### TAM evaluation system of ASSH

Score	%
Excellent	Normal
Good	>75
Fair	50-75
Poor	<50
Worse	< preoperative



Figure 23: Interphalangeal joint extension blocks





Figure 24 : Depiction of individual IP joint grip strength measurements using Kern hand grip dynamometer

# METHODOLOGY

After obtaining the Institutional Research Board (IRB) approval for conducting the study, a pilot trial was done. Patients with acute isolated flexor tendon injury who presented to the emergency department were sorted out according to the inclusion and exclusion criteria. Informed written consent was obtained from the appropriate patients for them to enrol in the study. The patients were operated on an emergency basis at an average time of within 8 hours of injury.

Computer generated randomised slips stating the type of surgical repair like ARM A-1 and ARM B-2, were kept in a sealed envelope and filed. The envelope file was kept in the operating room. Once the patient is taken up for surgery, after the initial debridement the operating surgeon decides if suitable surgical field is available for tendon repair. After proceeding for tendon repair, the surgeon asks the operating room personnel to open up the sealed envelope in order to see what type of repair has to be done- either a two-strand (Modified Kessler repair) or a four-strand (McLarney repair). Then the surgeon performs the repair as mentioned in the envelope for the tendons one by one starting from index finger to the little finger in that order ,with FDP repair done first followed by FDS repair.

All the tendons after the core suturing is done with 3-0 ethicon, the repair is completed by running epitendinous suture with 6-0 nylon. After the wound

closure and dressing, an above elbow cast is applied with the elbow in neutral position, wrist in 20 degree flexion, metacarpophalangeal joint in 80 degree flexion and interphalangeal joint in full extension.

All the patients were admitted to the post operative ward for observation and the limb is kept elevated with a pillow sling. On the fourth postoperative day, elastic traction is applied from the finger nail through a palmar pulley to the volar forearm and started on mobilisation according to the Kleinert passive motion protocol. They are discharged on the same day to be followed on a daily basis by a trained hand physiotherapist for 6 weeks. Mean while the patients are encouraged to do passive motion.

At the end of four weeks, the elbow cast is removed and a splint(cast) to maintain the wrist in a neutral position. Passive flexion-extension exercises and tendon gliding exercises are started and continued till 6 weeks. After 6 weeks, resisted exercises are started to improve the strength of repaired tendons. The patient are followed at regular intervals in the outpatient hand clinic for observing the parameters mentioned below till 6 months.

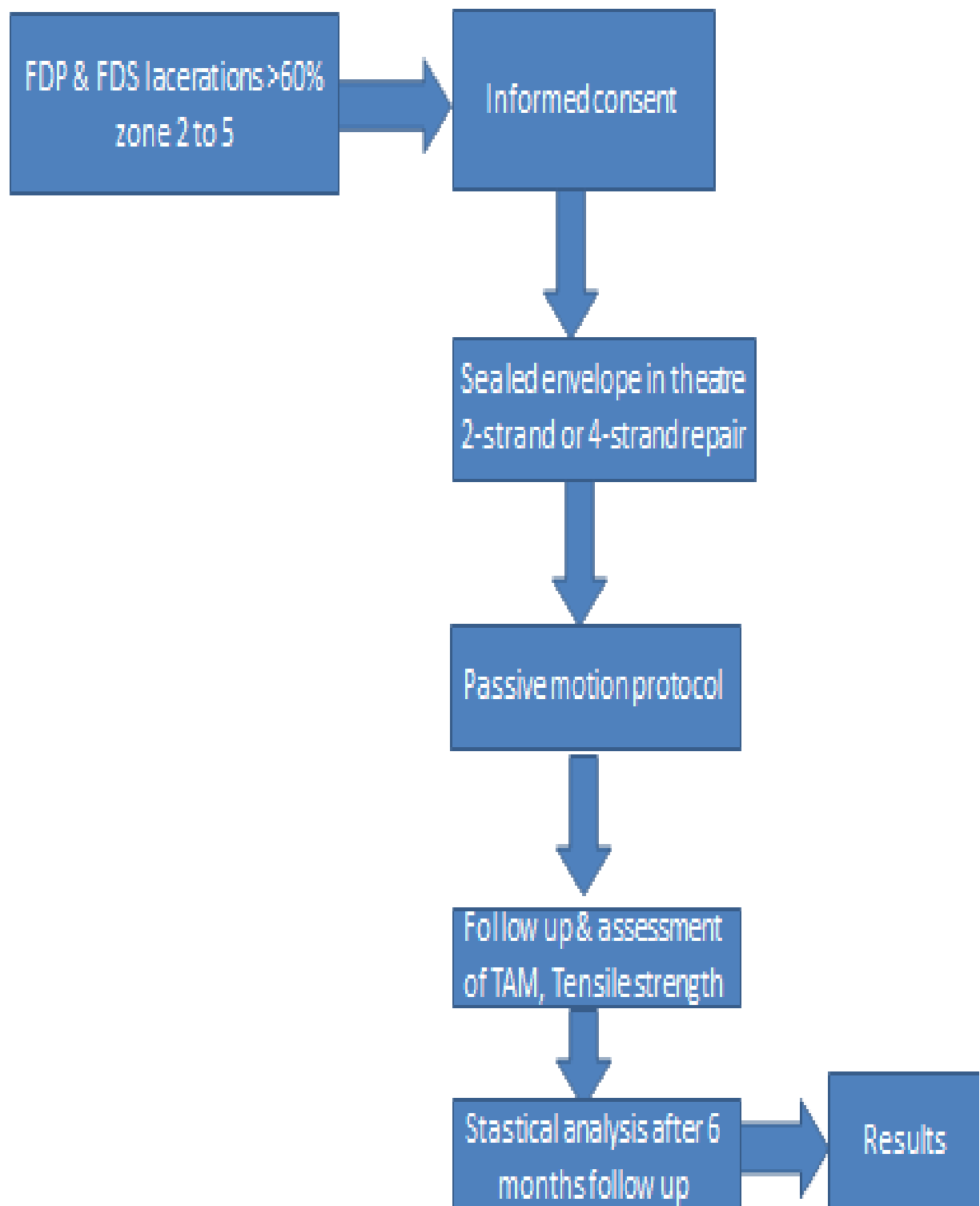
1. Range of motion of the fingers
2. Complications like rupture
3. Adhesions
4. Contractures



At the end of 6 months, the trained hand physiotherapist (blinded in the study) measures the following parameters.

1. Rupture of repaired tendons
2. Total active motion of proximal and distal interphalangeal joints of repaired and the contralateral normal fingers.
3. Individual Grip strength of the repaired fingers at the proximal and distal interphalangeal joints using a IP joint extension splints. Fig(
4. Adhesions

The parameters as recorded by the physiotherapist were handed over to the investigator for analysis, tabulation and inference of results.



## RESULTS

The variables of the randomised control study are analysed and tabulated as below.

#### DEMOGRAPHIC ANALYSIS :

TABLE 1 :

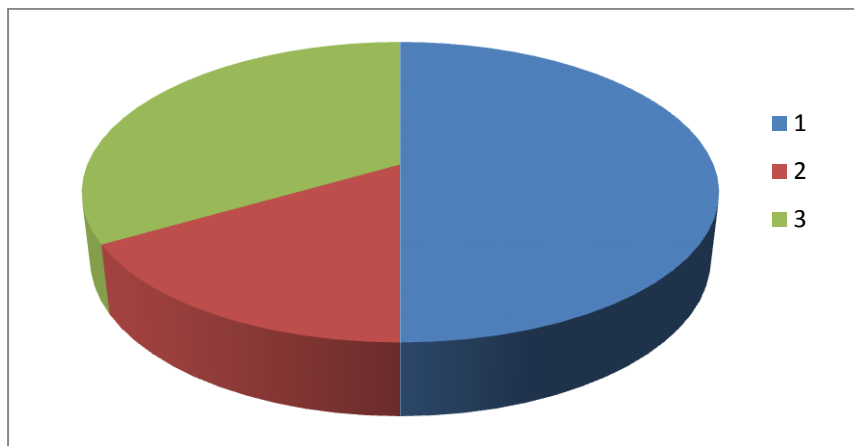
#### SEX ANALYSIS :

Sex	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Male	6	100.00	6	100.00

In this study, all the 6 patients under observation were males as shown in table 1.

DIAGRAM 1 :

#### AGE ANALYSIS



1- Age between 20-30

2- Age between 30-40

3- Age between 40-50

TABLE 2:

## OCCUPATION ANALYSIS

Occupation	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Light Work	1	16.67	1	16.67
Manual Labour	5	83.33	6	100.00

As given in table 2, among the 6 patients 5 were manual labourers and 1 was doing light work.

TABLE 3:

## INJURED SIDE ANALYSIS

Side	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Left	3	50.00	3	50.00
Right	3	50.00	6	100.00

Among the 6 patients, 3 persons had right hand injury and 3 persons had left hand injury as in table 3.

TABLE 4 :

## DOMINANT HAND ANALYSIS :

Dominant Hand				
Dominant_hand	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Right	6	100.00	6	100.00

All patients are right hand dominant individuals.

TABLE 5 : INCIDENCE ANALYSIS

Mode of Incidence				
MOI	Frequency	Percent	Cumulative Frequency	Cumulative Percent
ACCIDENTAL	2	33.33	2	33.33
INTENTIONAL	4	66.67	6	100.00

As in table 5, two patients had an accidental injury during work. The rest 4 patients had intentional glass cut injury.

TABLE 6 :

ZONE OF INJURY ANALYSIS :

Diagnosis	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Zone 2	1	16.67	1	16.67
Zone 5	5	83.33	6	100.00

Among the 6 patients , 1 had zone 2 injury & 5 patients had zone 5 injury as shown in table 6.

TABLE 7 ;

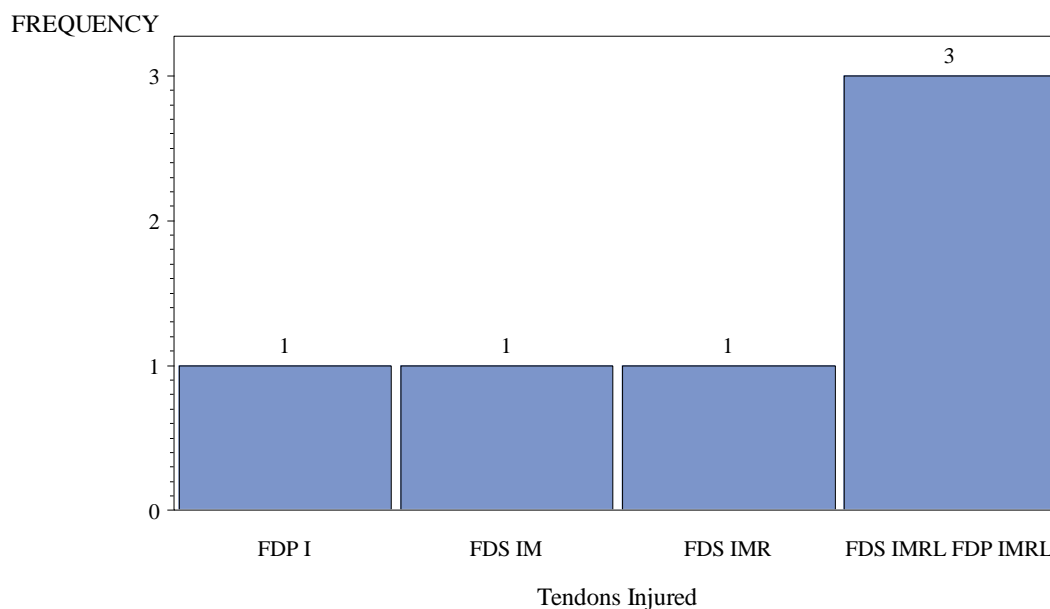
PREVIOUS HAND SURGERY

Previous Surgery				
Previous_surgery	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	6	100.00	6	100.00

None of the patients had any previous hand surgeries as evident in table 7.

DIAGRAM 2 :

NUMBER OF TENDONS INJURED:



As shown in the above diagram, three patients(FDS -IMRL FDP- IMRL) had full house injury ie.8 tendons. One patient had flexor digitorumsuperficialis(FDS- IMR) of index,middle&ring fingers ,one another patient had FDS injury (FDS-IM)of index and middle fingers and one had isolated flexor digitorumprofundus injury(FDP-I).

TABLE 8 :

RUPTURE ANALYSIS:

Rupture	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	30	100.00	30	100.00

As given in table 8, none of the repaired tendons were ruptured.

TABLE 9 :

## TOTAL ACTIVE MOTION ANALYSIS :

	Table of repair by Finger				
Repair(Technique of repair)		Finger			
Frequency Percent Row Pct Col Pct		Excellent	Good	Fair	Total
<b>2strand</b>		2	7	7	16
		6.67	23.33	23.33	53.33
		12.50	43.75	43.75	
		66.67	38.89	77.78	
<b>4strand</b>		1	11	2	14
		3.33	36.67	6.67	46.67
		7.14	78.57	14.29	
		33.33	61.11	22.22	
<b>Total</b>		3	18	9	30
		10.00	60.00	30.00	100.00

As shown in the above table, the total active motion was evaluated by ASSH score.

Among two-strand repaired tendons, 2 tendons had excellent score, 7 good and 7 fair. In the four- strand repaired tendons, 1 had excellent score, 11 had good score and 2 fair.



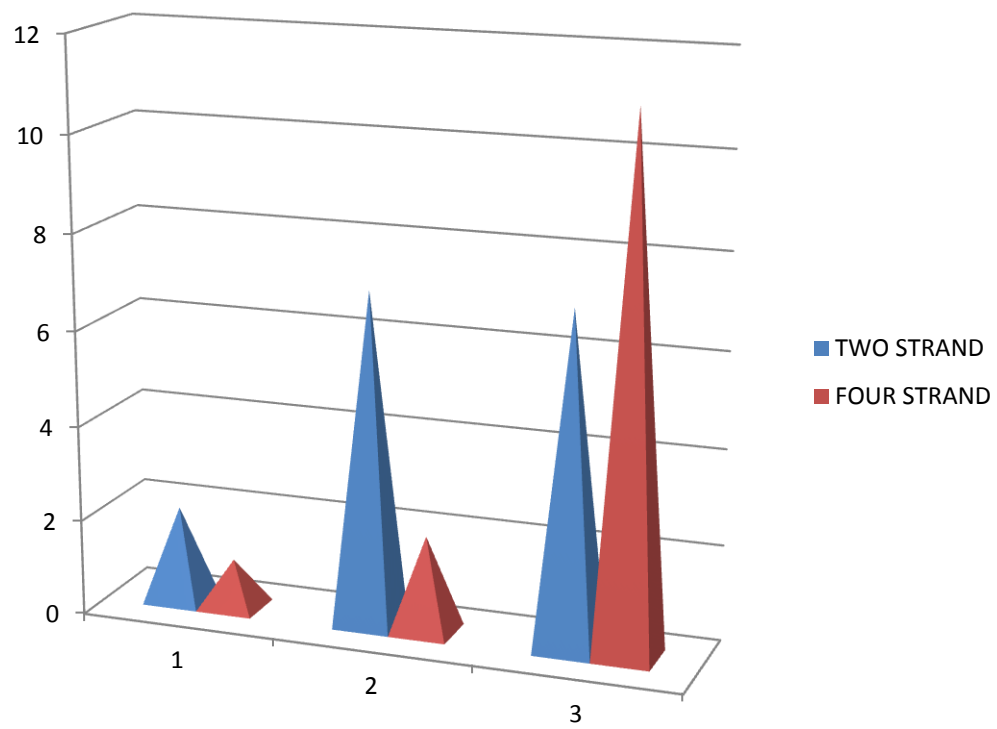


DIAGRAM 3 : Depicts the number of tendons repaired by two-strand and four-strand

TABLE10 :

SIGNIFICANCE OF TOTAL ACTIVE MOTION :

Fisher's Exact Test	
Table Probability (P)	0.0236
Pr<= P	0.1254

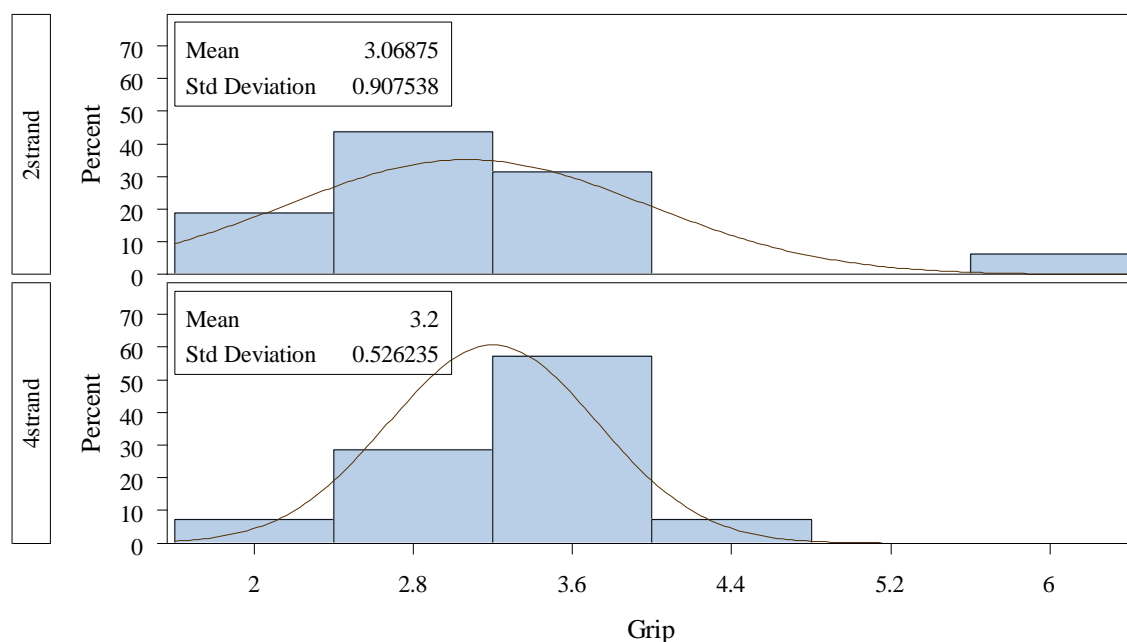
In the above table showing Fisher's exact test, the p value is found to be 0.1254(>0.05). This shows that there is no significant difference in total active motion between the two-strand and four-strand repaired tendons.

TABLE 11: GRIP STRENGTH:

VAR	N	Mean	Std Dev	Std Err	Minimum	Maximum
INJURY	6	16.8833	3.5205	1.4372	13.0000	23.0000
NORMAL	6	24.8667	4.0923	1.6707	21.0000	30.0000
Diff (1-2)		-7.9833	3.8171	2.2038		

As analysed in the table 9 by a t-test, the injured hand showed a mean grip of 16 /kg power with a maximum of 23/kg power and minimum of 13/kg power. In contrast the normal hand had a mean grip of 24/kg power with a maximum of 30/kg power and minimum of 21/kg power.

# DIAGRAM : CONFIDENCE INTERVAL OF GRIP STRENGTH BETWEEN TWO &FOUR STRAND



The above diagram shows the mean and standard deviation of the two and four strand repair

TABLE 12 :

TOTAL GRIP STRENGTH DIFFERENCE :

INJURY	NORMAL	Mean % Difference
16.8833	24.8667	32.10

In the above table, the mean difference of grip strength between the normal and injured hand is 32%. This shows that the patient has gained 70% grip strength in the injured hand as that of the normal hand.

TABLE13 :

## INDIVIDUAL GRIP STRENGTH :

Repair	N	Mean	Std Dev	Std Err	Minimum	Maximum
<b>2strand</b>	16	3.0688	0.9075	0.2269	2.1000	6.0000
<b>4strand</b>	14	3.2000	0.5262	0.1406	2.2000	4.2000
<b>Diff (1-2)</b>		-0.1312	0.7549	0.2762		

The above table shows the individual grip strength of two-strand versus four-strand measured by Kern hand grip dynamometer as described in the methodology. In this, the mean grip strength for two-strand repaired tendon is 3.0688/kg with a maximum of 6.000/kg and minimum of 2.1000/kg. The mean grip strength for four-strand repaired tendon is 3.2000/kg with a maximum of 4.2000/kg and minimum of 2.2000/kg.

TABLE14 :

## SIGNIFICANCE OF INDIVIDUAL GRIP STRENGTH :

Method	Variances	DF	t Value	Pr >  t
<b>Pooled</b>	Equal	28	-0.48	0.6384
<b>Satterthwaite</b>	Unequal	24.55 8	-0.49	0.6273

In the above table showing significance of individual grip strength , the p value is 0.6384 ( $>0.05$ ). this implies that there is no significant difference in grip strength between two-strand and four-strand repaired tendons.

TABLE 15:

ADHESION ANALYSIS :

Ahesions	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	30	100.00	30	100.00

In the above table, none of the repaired tendons developed adhesions in the postoperative period



Figure 25 : shows a study patient with Zone 5 flexor tendon injury with median and ulnar nerve injury in the postoperative follow-up demonstrating the range of motion of fingers



Figure 26 : shows a study patient in the postoperative period with clawing of hand and intrinsic wasting of muscles of hand who had associated median and ulnar nerve injury.



Figure 27: shows a study patient who developed contracture and stiffness in the post operative period due to non-compliance of rehabilitation



## **DISCUSSION**

Although there are multiple techniques evolved over decades for flexor tendon repair, still it is challenging for the hand surgeons to get a full functional outcome.

In this study, 6 patients with 30 tendon injuries underwent two techniques of repair ie. Two-strand(modified Kessler) and four –strand(McLarney ) repair. Based on the observation and results obtained in our study involving 6 patients with 16 tendons in two-strand repair group and 14 tendons in four-strand repair group are discussed in detail by comparing with the available evidence in the literature.

On analysing the demographic variables in terms of age, sex, occupation , we found that there was no significant difference among the patients under study(Tables 1,2 & diagram 1). On evaluating the handedness of the individual, it did not affect the prognosis of either type of repair technique used.

The study group chosen was limited to patients who had isolated flexor tendon injury since patients with associated fractures are exempted from participating. Patients with complex hand fractures will need atleast 6 weeks immobilisation in the postoperative period . In that case the patients will not be able to follow the Kleinert passive motion protocol. Patients with associated extensor tendon injuries were also exempted from enrolling in the study since the postoperative rehabilitation in them, differs from Kleinert protocol.

The sample size was calculated as 66 tendons with 33 in each arm, based on the literature evidence as described in methodology. But due to limitations in the follow up time period and non-compliance of one patient, the final study sample turned out to be 30 tendons. After randomisation, 16 tendons were repaired with two-strand technique and 14 were repaired with four-strand technique with a simple running epitendinous suture.

Most of the patients had a zone 5 injury in our study since the cause of injury was intentional. In contrast to other zones, injuries in zone 5 are more amenable to repair. In addition all patients with zone 5 injury had associated neurovascular injuries which were also repaired primarily.

In our study, four patients had all flexor tendons injured, among which one patient was excluded from the study due to non-compliance. The function of these patients were as good as patients with few tendons injured. The remaining three patients- one had associated both ulnar and median nerve injury and two had ulnar nerve injury. The patient with both nerve injury had clawing of fingers but their total active motion was good.

In our study, there was no rupture of repaired tendons either by two or four-strand technique following rehabilitation by Kleinert protocol. Elliot et al in 1994 reported in adults a 5.8% rupture rate in fingers and 16.8% in thumb following early active motion protocol<sup>48</sup>. Becker H et al(1979) followed early active motion protocol for flexor tendons repaired with a bevelled technique and

had a 10% rupture rate. In children the rupture rate is high because of the difficulty in educating children the postoperative rehabilitation protocol. The rupture rate is found to be higher in the youngest age group<sup>38</sup>.

The total active motion was measured by American society for surgery of hand (ASSH) scoring system. We had 3 excellent, 18 good and 9 fair results in all fingers. The four-strand repair had 11 good results and the two-strand had 7 fair results. But there was no statistical difference between the two-strand or four-strand repair in terms of total active motion. Strickland JW evaluated the result of flexor tendon surgery in zone II those with primary tendon repair had 56% excellent or good results, 13% poor category and 4% had rupture of tendon<sup>49</sup>.

There is reduction in the total grip strength of the injured hand, especially when there is associated ulna and median nerve injury.(50) In our study also there was reduction in the grip strength than the normal but they gained 70% grip strength of the normal hand. Chan TK et al evaluated the functional outcome of hand following flexor tendon repair in zone II with modified Kessler repair. They found that the injured hand had a grip strength of 78% that of uninjured hand<sup>51</sup>. In a study done by Rajapa et al, flexor tendons repaired by six-strand Triple Kessler repair the mean grip strength was 80% of normal in dominant hand and 60% of normal in non-dominant hands<sup>52</sup>.

# SUMMARY

A double blind randomised controlled study was designed to compare the two- strand(modified Kessler) and four-strand(McLarney) techniques of flexor tendon repair in adult population. Based on the analysis of the results and discussion in our study, the conclusions arrived at are summarized as below.

In our study,

- The demographic variables such as age, sex, occupation are comparable between the groups
- There was no rupture of repaired tendons by either of the two techniques.
- The total active motion was found to be good to excellent in most repaired fingers by both techniques and there was no statistically significant difference between the groups.
- The total grip strength was evaluated in our study and we found that the injured hand gained a mean grip strength of 70% that of the normal hand.
- The individual grip strength between these two techniques was measured and there was no statistical difference among them( Even though the individual grip strength measuring method was not standardised)
- There was no adhesion found in the repaired tendons.
- One patient developed flexion contracture postoperatively due to noncompliance.

- Patients with zone V injury had an associated median and ulnar nerve injuries which was also repaired primarily with an incomplete neurological recovery.

## **CONCLUSION**



We conclude that there is no statistical difference between two-strand(modified Kessler) and four-strand(McLarney) techniques of flexor tendon repair following a Kleinert Passive Motion Protocol in terms of rupture, total active motion, grip strength and adhesion on in vivo testing

## REFERENCES

1. Robert Collyer. 1823–1912. English-born American orator.
2. Kleinert HE, Spokevicius S, Papas NH. History of flexor tendon repair. *J Hand Surg.* 1995 May;20(3 Pt 2):S46–52.
3. Chamay A. [The history of flexor tendon surgery]. *Ann Chir Main Memb Supér Organe Off Sociétés Chir Main Ann Hand Up Limb Surg.* 1997;16(1):9–15.
4. Mehling IM, Arsalan-Werner A, Sauerbier M. Evidence-based Flexor Tendon Repair. *Clin Plast Surg.* 2014 Jul;41(3):513–23.
5. Doyle, James R.; Botte, Michael J. *Surgical Anatomy of the Hand and Upper Extremity*, 1st Edition.
6. Campbell's Operative Orthopaedics 11th Edition.
7. Sebastin SJ, Ho A, Karjalainen T, Chung KC. History and evolution of the Kessler repair. *J Hand Surg.* 2013 Mar;38(3):552–61.
8. McLarney E, Hoffman H, Wolfe SW. Biomechanical analysis of the cruciate four-strand flexor tendon repair. *J Hand Surg.* 1999 Mar;24(2):295–301.
9. Bunnell.S. Reconstructive surgery of the hand. *Surg Gynecol Obstet* 1924;39:259.
10. Matev I, Karagancheva S, Trichkova P, Tsekov P. Delayed primary suture of flexor tendons cut in the digital theca. *The Hand.* 1980 Jun;12(2):158–62.
11. Stone JF, Davidson JS. The role of antibiotics and timing of repair in flexor tendon injuries of the hand.
12. Salvi V. Delayed primary suture in flexor tendon division. *Hand* 1971;3:181–183.
13. Gorris GJ, Cooke J. Assessment of the influence of the timing of repair on flexor tendon injuries in chickens. *Br J Plast Surg.* 1976;29:82–84.
14. Gulihar A, Hajipour L, Dias JJ. Comparison of three different peripheral suturing techniques for partial flexor tendon lacerations: A controlled in-vitro biomechanical study. *Hand Surg.* 2012;17:155–160.
15. Amis AA WP, Wetherell RG,. Flexor tendon repair: Significant gain in strength from the Halsted peripheral suture technique. *J Hand Surg Br.* 1989;14:232–235.
16. Silfverskildö K, May EJ. Flexor tendon repair in zone II with a new suture technique an early mobilization program combining passive and active flexion. *J Hand Surg Am.* 1994;19:53–60.
17. Kim PT, Aoki M, Tokita F, Ishii S. Tensile strength of cross-stitch epitendon suture. *J Hand Surg Edinb Scotl.* 1996 Dec;21(6):821–3.
18. Diao E, Hariharan JS, Soejima O, Lotz JC. Effect of peripheral suture depth on strength of tendon repairs. *J Hand Surg.* 1996 Mar;21(2):234–9.

19. Merrell GA, Wolfe SW, Kacena WJ, Gao Y, Cholewicki J, Kacena MA. The effect of increased peripheral suture purchase on the strength of flexor tendon repairs. *J Hand Surg.* 2003 May;28(3):464–8.
20. Green WL, Niebauer JJ. Results of primary and secondary flexor-tendon repairs in no man's land. *J Bone Joint Surg Am.* 1974;56:1216–1222.
21. Pike JM, Gelberman RH. Zone II combined flexor digitorum superficialis and flexor digitorum profundus repair distal to the A2 pulley. *J Hand Surg Am.* 2010;35:1523–1527.
22. Strickland JW. Development of flexor tendon surgery: Twentyfive years of progress. *J Hand Surg Am.* 2000;25:214–235.
23. Leffelt M, Ray E, Sherman R. Treatment of flexor tendon laceration. *Plast Reconstr Surg.* 2008;121:1–12.
24. Taras JS, Raphael JS, Marczyk SC, Bauerle WB. Evaluation of suture caliber in flexor tendon repair. *J Hand Surg Am.* 2001;26:1100–1104.
25. Zhao C, Amadio PC, Zobitz ME, An KN. Resection of the flexor digitorum superficialis reduces gliding resistance after zone II flexor digitorum profundus repair in vitro. *J Hand Surg Am.* 2002;27:316–321.
26. Paillard PJ, Amadio PC, Zhao C, Zobitz ME, An KN. Pulley plasty versus resection of one slip of the flexor digitorum superficialis after repair of both flexor tendons in zone II: A biomechanical study. *J Bone Joint Surg Am.* 2002;84:2039–2045.
27. Griffin M, Hindocha S, Jordan D, Saleh M, Khan W. An overview of the management of flexor tendon injuries. *Open Orthop J.* 2012;6:28–35.
28. Kotwal PP, Ansari MT. Zone 2 flexor tendon injuries: Venturing into the no man's land. *Indian J Orthop.* 2012;46:608–615.
29. Vizesi F, Jones C, Lotz N, Gianoutsos M, Walsh WR. Stress relaxation and creep: viscoelastic properties of common suture materials used for flexor tendon repair. *J Hand Surg.* 2008 Feb;33(2):241–6.
30. Lawrence TM, Davis TRC. A biomechanical analysis of suture materials and their influence on a four-strand flexor tendon repair. *J Hand Surg.* 2005 Jul;30(4):836–41.
31. Haimovici L, Papafragkou S, Lee W, Dagum A, Hurst LC. The impact of fiberwire, fiberloop, and locking suture configuration on flexor tendon repairs. *Ann Plast Surg.* 2012 Oct;69(4):468–70.
32. Thurman RT, Trumble TE, Hanel DP, Tencer AF, Kiser PK. Two-, four-, and six-strand zone II flexor tendon repairs: an in situ biomechanical comparison using a cadaver model. *J Hand Surg.* 1998 Mar;23(2):261–5.
33. Dinopoulos HT, Boyer MI, Burns ME, Gelberman RH, Silva MJ. The resistance of a four- and eight-strand suture technique to gap formation during tensile testing: an experimental study of repaired canine flexor tendons after 10 days of in vivo healing. *J Hand Surg.* 2000 May;25(3):489–98.

34. Barrie KA, Wolfe SW, Shean C, Shenbagamurthi D, Slade JF, Panjabi MM. A biomechanical comparison of multistrand flexor tendon repairs using an in situ testing model. *J Hand Surg.* 2000 May;25(3):499–506.
35. Seradge H, Tian W, Kashef GH, Seradge A, Owen W. The Oklahoma repair technique: a biomechanical study of a new suture repair technique. *J Okla State Med Assoc.* 2000 Dec;93(12):551–6.
36. Navali AM, Rouhani A. Zone 2 Flexor Tendon Repair in Young Children: A Comparative Study of Four-Strand Versus Two-Strand Repair. *J Hand Surg Eur Vol.* 2008 Aug 1;33(4):424–9.
37. Wu YF, Cao Y, Zhou YL, Tang JB. Biomechanical comparisons of four-strand tendon repairs with double-stranded sutures: effects of different locks and suture geometry. *J Hand Surg Eur Vol.* 2011 Jan 1;36(1):34–9.
38. Al-Qattan MM. A six-strand technique for zone II flexor-tendon repair in children younger than 2 years of age. *Injury.* 2011 Nov;42(11):1262–5.
39. Peltz TS, Haddad R, Scougall PJ, Nicklin S, Gianoutsos MP, Walsh WR. Influence of locking stitch size in a four-strand cross-locked cruciate flexor tendon repair. *J Hand Surg.* 2011 Mar;36(3):450–5.
40. Al-Qattan MM, Al-Rakan MA, Al-Hassan TS. A biomechanical study of flexor tendon repair in zone II: comparing a combined grasping and locking core suture technique to its grasping and locking components. *Injury.* 2011 Nov;42(11):1300–2.
41. Tang JB, Zhang Y, Cao Y, Xie RG. Core suture purchase affects strength of tendon repairs. *J Hand Surg.* 2005 Nov;30(6):1262–6.
42. Schuind F, Garcia-Elias M, Cooney WP, An KN. Flexor tendon forces: in vivo measurements. *J Hand Surg.* 1992 Mar;17(2):291–8.
43. Vucekovich K, Gallardo G, Fiala K. Rehabilitation after flexor tendon repair, reconstruction, and tenolysis. *Hand Clin.* 2005 May;21(2):257–65.
44. Collins DC, Schwarze L. Early progressive resistance following immobilization of flexor tendon repairs. *J Hand Ther* 1991;4:111–6.
45. Freehan LM, Beauchene JG. Early tensile properties of healing flexor tendons: early controlled passive motion versus postoperative immobilization. *J Hand Surg* 1990;15A:63–8.
46. Gelberman RH, Vandeberg JS, Manske PR, Akeson, WH. The early stages of flexor tendon healing: a morphologic study of the first fourteen days. *J Hand Surg [Am]* 1985;10:776–84.
47. Zhao C, Amadio PC, Zobitz ME, An K. Sliding characteristics of tendon repair in canine flexor digitorum profundus tendons. *J Orthop Res* 2001;19: 580–6.
48. Elliot D, Moiemmen NS, Flemming AF, Harris SB, Foster AJ. The rupture rate of acute flexor tendon repairs mobilized by the controlled active motion regimen. *J Hand Surg Edinb Scotl.* 1994 Oct;19(5):607–12.
49. Strickland JW. Results of flexor tendon surgery in zone II. *Hand Clin.* 1985 Feb;1(1):167–79.

50. Gault DT. Reduction of grip strength, finger flexion pressure, finger pinch pressure and key pinch following flexor tendon repair. *J Hand Surg Edinb Scotl.* 1987 Jun;12(2):182–4.
51. Chan TK, Ho CO, Lee WK, Fung YK, Law YF, Tsang CY. Functional outcome of the hand following flexor tendon repair at the “no man”’s land’. *J Orthop Surg Hong Kong.* 2006 Aug;14(2):178–83.
52. Rajappa S, Menon PG, Kumar MM, Raj DG. Early active motion protocol following triple Kessler repair for flexor tendon injury. *J Orthop Surg Hong Kong.* 2014 Apr;22(1):96–9.

## ANNEXURES

### CONSENT FORM

Informed Consent form to participate in a research study

Study Title: Double blind randomised control trial of two-Strand vs four- Strand flexor tendon repair

Study Number: \_\_\_\_\_

Subject's Initials: \_\_\_\_\_ Subject's Name: \_\_\_\_\_

Date of Birth / Age: \_\_\_\_\_

I , we have been explained about the study and procedure used to treat us. We have been explained about the benefits like early functional recovery and risk like rupture, redo surgery, adhesions, of the two standardised technique of flexor tendon repairs, 2-Strand and 4- Strand ( McLaren technique) .

(i) I confirm that I have read and understood the information sheet dated \_\_\_\_\_ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Signatory's Name: \_\_\_\_\_

Signature of the Investigator: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Study Investigator's Name: \_\_\_\_\_

Signature of the Witness: \_\_\_\_\_

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Name of the Witness: \_\_\_\_\_

## PROFORMA

### CASE REPORT SHEET FOR RCT OF 2-STRAND VS 4-STRAND FLEXOR TENDON REPAIR

NAME:

Age:

Sex:

Hospital number:

Address:

Occupation:

Diagnosis:

Dominant hand:

Previous hand surgeries: yes/ no

Side:

Complications:

Rupture: 1-yes 2- no

TAM: PIP Date:

	I.Index	I.Middle	I.Ring	I.Little	Index	Middle	Ring	Little
TAM								
Score								

TAM: DIP Date:

Date:

	I.Index	I.Middle	I.Ring	I.Little	Index	Middle	Ring	Little
TAM								
Score								

DPD:

	I.Index	I.Middle	I.Ring	I.Little	Index	Middle	Ring	Little
Active								
Passive								

Tensile strength:

	I.Index	I.Middle	I.Ring	I.Little	Index	Middle	Ring	Little
PIP								
DIP								

Assessed:

Date:



## **DOUBLE BLIND RANDOMIZED CONTROL TRIAL OF 2-STRAND VERSUS 4-STRAND FLEXOR TENDON REPAIR**

### **PATIENT INFORMATION SHEET**

The [flexor tendon](#) system of the [hand](#) consists of the flexor muscles of the [forearm](#), their tendinous extensions, and the specialized digital flexor sheaths. These components work in concert to produce smooth and efficient flexion of the individual digits of the hand. Injury to the [flexor tendon](#) system can lead to significant morbidity for patients.

There are different techniques for repairing flexor tendon, 2-Strand, 4-Strand, 6-Strand, 8-Strand and modification in the above techniques. The strand corresponds to the longitudinal suture, sutured across the severed tendon. The 2-Strand repair technique is simple, requires less suture material, the surgery time is less and doesn't require a trained hand surgeon. The 4-Strand repair is technically difficult, will require more suture material, the surgery time is long, will require a trained hand surgeon. The techniques are found to be superior over the other by the strength of the repair which has been studied only invitro. The clinical outcome has not been studied in adult population. So by this study the clinical outcome between the two techniques can be compared.

Participating in the study is entirely voluntary and you can decide to withdraw from the study at any point in time. This will not affect the treatment you will be undergoing in this hospital. If you are not willing to participate in the study also the standard of care will be given to you.

#### **If you take part in this study what will you have to do?**

- i. Sign a consent form
- ii. Come regularly for follow up and physiotherapy for 6 months.

#### **Is there any complications?**

There is no complication due to the technique per-se.

**What are the benefits of the study?**

If it is proved that the two techniques are similar, the suture material, the time of suturing and adhesion will be reduced. The 2-Strand technique can be done by surgeon in primary and secondary care center.

**Will your personal details be kept confidential?**

The results of this study will be published in a medical academic journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission.

**Can you withdraw from this study after it starts?**

Participation in this study is all voluntary; patient can withdraw from the study at any time. Refusal to participate will not involve any loss of benefits to which subject is otherwise entitled.

**In case of any emergency or doubt contact**

Dr. Santhosh Kumar G,

P.G. Registrar,

Department of Orthopaedics,

Paul Brand Building,

CMC,

Vellore.

Phone No. 04162282924, 8056886588

# IRB APPROVAL



## OFFICE OF RESEARCH INSTITUTIONAL REVIEW BOARD (IRB) CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

**Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)**  
Director, Christian Counseling Center,  
Chairperson, Ethics Committee.

**Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho**  
Chairperson, Research Committee & Principal

**Dr. Nihal Thomas,**  
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Glas) (EDIN)  
Deputy Chairperson  
Secretary, Ethics Committee, IRB  
Additional Vice Principal (Research)

January 02, 2014

Dr. Santhosh Kumar. G  
PG Registrar  
Department of Orthopaedics  
Christian Medical College, Vellore 632 002

Sub: **Fluid Research grant project:**  
Double blind randomized control trial of two strand versus four strand  
flexor tendon repair in adults.  
Dr. Santhosh Kumar. G, Orthopaedics, Dr. Binu Prathap Thomas, Dr. Paul  
Brand Centre for Hand Surgery, Leprosy Recon. Surgery and Peripheral  
Nerve Surgery, Dr. Anil Mathew, Dr. Sreekanth. R, Dr. Kiran Sasi. P

Ref: IRB Min. No 9523 [INTERVEN] dated 30.10.2013

Dear Dr. Santhosh Kumar. G

I enclose the following documents:

1. Institutional Review Board approval
2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal  
(Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas  
Secretary (Ethics Committee)  
Institutional Review Board

**Dr. NIHAL THOMAS**  
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)  
SECRETARY - (ETHICS COMMITTEE)  
Institutional Review Board,  
Christian Medical College, Vellore - 632 002.

Cc: Dr. Binu Prathap Thomas, HLRS & PNS, CMC

1 of 6

## EPIDATA FORM

Name	Patient Name
Hospital Number	ID Number of patient
Age	Age of patient
##	
Exploratory	
Sex	Gender of patient
#	1"Male" 2"Female"
Address	Address of pt
#	1"Vellore Municipal" 2"Vellore Dist" 3"Rest of
Tamil Nadu" 4"AP"	
Occupation	Occupation of pt
#	1"Manual Labour" 2"Bench Work"
Side	Injured side
#	1"Right" 2"Left"
MOI	Mode injury
#	1"accidental" 2"suicidal" 3"homicidal"
D H	Dominant hand
#	1"Right" 2"Left"
Diagnosis	Diagnosis
	1"Zone 1" 2"Zone 2" 3"Zone 3" 4"Zone 4" 5"Zone
5"	
DOS	Date of surgery
<dd/mm/yyyy>	
Tendons injured	Injured tendons in each finger
	1"FDS" IMRL 2"FDP" IMRL
Previous surgery	Prev Hand surgery
#	1"yes" 2"no"
Rupture of tendon	Rupture of tendon
#	1"yes" 2"no"
Ruptured tendon	Tendon which is ruptured
TAM PIP Inj IF	Total Active Motion PIP of injured index
finger #	1-Excellent 2-good 3-fair 4-poor
5-worse	
Repair	Technique used to repair
#	1-2strand 2-4strand
TAM PIP Inj MF	Total Active Motion PIP of injured middle
finger #	1-Excellent 2-good 3-fair 4-poor
5-worse	
Repair	Technique used to repair
#	1-2strand 2-4strand
TAM PIP Inj RF	Total Active Motion PIP of injured ring finger
#	1-Excellent 2-good 3-fair 4-poor 5-worse
Repair	Technique used to repair
#	1-2strand 2-4strand
TAM PIP Inj LF	Total Active Motion PIP of injured little
finger #	1-Excellent 2-good 3-fair 4-poor
5-worse	
Repair	Technique used to repair
#	1-2strand 2-4strand
TAM DIP Inj IF	Total Active Motion DIP of injured index
finger #	1-Excellent 2-good 3-fair 4-poor
5-worse	
Repair	Technique used to repair
#	1-2strand 2-4strand
TAM DIP Inj MF	Total Active Motion DIP of injured middle
finger #	1-Excellent 2-good 3-fair 4-poor
5-worse	
Repair	Technique used to repair
#	1-2strand 2-4strand
TAM DIP Inj RF	Total Active Motion DIP of injured ring finger
#	1-Excellent 2-good 3-fair 4-poor 5-worse

Repair	Technique used to repair
#	1-2strand 2-4strand
TAM DIP Inj LF	Total Active Motion DIP of injured little
finger #	1-Excellent 2-good 3-fair 4-poor
5-worse	
Repair	Technique used to repair
#	1-2strand 2-4strand
Gr Strength PIP Inj IF	Grip strength of injured index finger
###.##	
Gr Strength PIP Inj MF	Grip strength of injured middle finger
###.##	
Gr Strength PIP Inj RF	Grip strength of injured ring finger
###.##	
Gr Strength PIP Inj LF	Grip strength of injured little finger
###.##	
Gr Strength DIP Inj IF	Grip strength of injured index finger
###.##	
Gr Strength DIP Inj MF	Grip strength of injured middle finger
###.##	
Gr Strength DIP Inj RF	Grip strength of injured ring finger
###.##	
Gr Strength DIP Inj LF	Grip strength of injured little finger
###.##	
TAM PIP IF	Total Active Motion
#	1-Excellent 2-good 3-fair 4-poor 5-worse
TAM PIP MF	Total Active Motion
#	1-Excellent 2-good 3-fair 4-poor 5-worse
TAM PIP RF	Total Active Motion
#	1-Excellent 2-good 3-fair 4-poor 5-worse
TAM PIP LF	Total Active Motion
#	1-Excellent 2-good 3-fair 4-poor 5-worse
TAM DIP IF	Total Active Motion
#	1-Excellent 2-good 3-fair 4-poor 5-worse
TAM DIP MF	Total Active Motion
#	1-Excellent 2-good 3-fair 4-poor 5-worse
TAM DIP RF	Total Active Motion
#	1-Excellent 2-good 3-fair 4-poor 5-worse
TAM DIP LF	Total Active Motion
#	1-Excellent 2-good 3-fair 4-poor 5-worse
Gr Strength PIP IF	Grip strength
###.##	
Gr Strength PIP MF	Grip strength
###.##	
Gr Strength PIP RF	Grip strength
###.##	
Gr Strength PIP LF	Grip strength
###.##	
Gr Strength DIP IF	Grip strength
###.##	
Gr Strength DIP MF	Grip strength
###.##	
Gr Strength DIP RF	Grip strength
###.##	
Gr Strength DIP LF	Grip strength
###.##	
Total Gr Str of inj hand	Total grip strength of injured hand
###.##	
Total Gr Str of norm hand	Total grip strength of normal hand
###.##	
Ahesions	Adhesion of the tendon
#	1- yes, 2- no
Date	Date of examination
<dd/mm/yyyy>	

**EPIDATA EXPORT SHEET**

name	hospital	age	sex	address	occupation	side	moi	d	diagnosis
Damodharan	754988f	42	1	2	1	1	2	1	5
Arulkumar	901302f	25	1	2	1	2	1	1	5
Kamaraj	901838f	39	1	2	1	2	2	1	5
SEKAR	902871F	29	1	1	1	1	2	1	5
Velusamy	355818b	48	1	4	2	2	1	1	2
Rasak Basha	904337f	20	1	1	1	1	2	1	5

repair2	tam3	repair3	tam4	repair4	tam5	repair5	tam6	repair6	tam7	repair7
2	2	1	2	2	3	1	2	2	2	1
2	2	1	3	1	1	1	2	2	3	1
2	3	1	2	2	3	1	3	1	3	2
2			2	2						

tam10	tam11	tam12	tam13	tam14	tam15	gr8	gr9	gr10	gr11	gr12
1	1	1	1	1	1	7.5	8	5.6	3.5	5.8
1	1	1	1	1	1	11	12.8	7	5.7	4.4
1	1	1	1	1	1	5.3	8.8	7.5	5.2	4.4
1						5.4	8.9	7.5		
		1								4.4
						5.4	8.8	7.5	5.4	